

## World Trade Center Health Program, Clinical Center of Excellence Performance Work Statement

### C.1 Background

On January 2, 2011, the President signed Public Law No. 111-347, the James Zadroga 9/11 Health and Compensation Act (“Zadroga Act”), providing a longer-term solution to care for the World Trade Center (WTC) responders and survivors. Title I of the Zadroga Act amended the Public Health Service Act to add Title XXXIII, which authorized the WTC Health Program as a federal health care program, within the Department of Health and Human Services, for eligible responders and survivors of the terrorist attacks of 9/11. *See* “James Zadroga 9/11 Health and Compensation Act of 2010,” Public Law 111-347, as amended by Public Law 114-113 (codified at 42 U.S.C. §§ 300mm – 300mm-61). The Zadroga Act can be found at: <http://uscode.house.gov/view.xhtml?req=granuleid%3AUSC-prelim-title42-chapter6A-subchapter31&edition=prelim>. The Zadroga Act encompasses myriad responsibilities associated with the administration and performance needed to enroll, initially evaluate, medically monitor, and manage covered health conditions for eligible individuals through diagnostic and treatment services. Responsibilities include the construction of a comprehensive medical and pharmaceutical benefit program consistent with a limited care model; similar in constraints to a worker compensation model, yet requiring the flexibility to engage with advocates and stakeholders. To align with legal requirements, the WTC Health Program promulgated regulations guiding program implementation and created member-based health benefit plans restricted to the conditions certified by the WTC Health Program Administrator for coverage. In addition, a new business processing component was developed to adjudicate and pay medical and pharmacy claims from enrolled providers for allowable services authorized by Clinical Centers of Excellence (CCEs) to manage the care of a restricted set of health conditions for eligible program members. Required administrative processes included procedures for appeals related to denials of program enrollment, health condition certification, or treatment bills. The WTC Health Program had to be operational within 6 months of the passage of the authorizing legislation - by July 1, 2011.

In Spring 2011, the CDC entered into contracts with seven Clinical Centers of Excellence (as defined in subsection (b)(1)(A)) for the following tasks:

#### “SEC. 3305. CLINICAL CENTERS OF EXCELLENCE AND DATA CENTERS.

“(a) IN GENERAL.—

“(A) for the provision of monitoring and treatment benefits and initial health evaluation benefits under sub- title B;

“(B) for the provision of outreach activities to individuals eligible for such monitoring and treatment benefits, for initial health evaluation benefits, and for follow up to individuals who are enrolled in the monitoring program; “(C) for the provision of counseling for benefits under subtitle B, with respect to WTC-related health conditions, for individuals eligible for such benefits;

“(D) for the provision of counseling for benefits for WTC-related health conditions that may be available under workers’ compensation or other benefit programs for work-related injuries or illnesses, health insurance, disability insurance, or other insurance plans or through public or private social service agencies and assisting eligible individuals in applying for such benefits;

“(E) for the provision of translational and interpretive services for program participants who are not English language proficient; and

“(F) for the collection and reporting of data, including claims data, in accordance with section 3304.<sup>1</sup>

As of March 31, 2016, the WTC Health Program has 74,968 members enrolled, including 16,896 FDNY responders, 49,302 general responders and 9,770 survivors. Of those members, 8,414 responders, 203 FDNY and 890 survivors

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<sup>1</sup> Section (F) refers to a requirement for the CCE. Currently the WTC Health Program has been able to facilitate the process more efficiently by providing claims data directly to the Data Centers through the health support contractor without requiring the CCEs to do so. This could change with the implementation of new contracts.

are served by the Nationwide Provider Network. The Program delivered monitoring or screening exams to an estimated 30,332 members, diagnostic services to approximately 18,850 members, and treatment services to approximately 23,283 sick or injured members between 4/1/15 and 3/31/16. Current WTC Health Program statistics and reports can be found at [http://www.cdc.gov/wtc/reports\\_portal.html](http://www.cdc.gov/wtc/reports_portal.html).

### **C.1.1 Clinical Centers of Excellence and the Nationwide Provider Network**

There are currently seven Clinical Centers of Excellence (CCEs) and one Nationwide Provider Network (NPN) that provide medical monitoring examinations, diagnosis, and treatment services for the WTC-related health conditions. One CCE serves the members affiliated with the Fire Department of the City of New York (FDNY) WTC Responders, five CCEs serve a General WTC Responder consortium, one CCE serves WTC Survivors, and the NPN serves enrolled members located elsewhere in the U.S. Treatment services include physician visits, test procedures, medical devices, pharmacy benefits, case management, care coordination, health education, and social benefits counseling. The CCEs and NPN work as a clinical consortium with cohort-specific standardized medical monitoring protocols, shared diagnostic and treatment guidelines and multiple opportunities for communication with WTC Health Program Staff and each other to calibrate medical and member benefits across practice sites. The CCEs and NPN are actively engaged with labor representatives and stakeholder members of the New York City community to discuss program policies and ensure awareness of emerging issues.

### **C.1.2 Member Classifications**

The CCE contractor must indicate member cohort classification(s) to be served, either FDNY Responders, Non-FDNY Responders, and/or Survivors.

The Pentagon/Shanksville, PA Responders are being served by the NPN contractor.

Below are descriptions for the four (4) classifications of the WTC Health Program members being served by the CCEs and the NPN.

#### **(1) Enrolled WTC Responders affiliated with the Fire Department of the City of New York**

Approximate size: 16,520. An individual (active or retired) who participated at least one day in the rescue and recovery effort at any of the former World Trade Center sites (including Ground Zero, Staten Island Landfill, and the New York City Chief Medical Examiner's Office), or; a surviving immediate family member of a member of the Fire Department of New York City (whether fire or emergency personnel, active or retired) who was killed at the World Trade Center site on September 11, 2001, if the family member received any treatment for a WTC-related mental health condition on or before September 1, 2008;

#### **(2) Enrolled WTC Responders who were not affiliated with FDNY (Non-FDNY Responders)**

Approximate size: 39,869. An individual who worked or volunteered onsite in rescue, recovery, demolition, debris cleanup, or related support services in lower Manhattan (south of Canal St.), the Staten Island Landfill, or the barge-loading piers; a member of the Police Department of New York City (active or retired) or a member of the Port Authority Police of the Port Authority of New York and New Jersey (active or retired) who participated onsite in rescue, recovery, debris cleanup, or related services in lower Manhattan (south of Canal St.), including Ground Zero, the Staten Island Landfill, or the barge loading piers; an employee of the Office of the Chief Medical Examiner of New York City involved in the examination and handling of human remains from the World Trade Center attacks, or other morgue worker who performed similar post-September 11 functions for such Office staff; a worker in the Port Authority Trans-Hudson Corporation Tunnel; or a vehicle-maintenance worker who was exposed to debris from the former World Trade Center while retrieving, driving, cleaning, repairing, and maintaining vehicles contaminated by airborne toxins from the September 11, 2001, terrorist attacks;

#### **(3) Enrolled WTC Survivors**

Approximate size: 9,770. Individuals present in the New York City disaster area in the dust or dust cloud on September 11, 2001; an individual who lived, worked, went to school, childcare, or adult daycare in lower Manhattan south of Houston Street and certain parts of Brooklyn; certain cleanup and maintenance workers in

the New York City disaster area; and certain residents and individuals whose place of employment were deemed eligible to receive certain grants from the Lower Manhattan Development Corporation; and

**(4) Pentagon/Shanksville, PA Responders**

Approximate size: 297. Fire or police department employees (fire or emergency personnel, active or retired); recovery or cleanup contractor workers; or volunteers, who performed rescue, recovery, demolition, debris cleanup, or other related services after the terrorist-related aircraft crashes on September 11, 2001, at the Pentagon in Arlington VA, or in Shanksville, PA.

In this Performance Work Statement (PWS), “members” indicates responders or survivors who are assigned to a specific CCE. Also note, that where Section or Subsection Numbers are specified, those sections refer to the appropriate Section or Subsection Numbers of the Zadroga Act. The following table shows the CCE and its corresponding Data Center.

**Table 1 Current Data Centers and Corresponding Clinical Centers of Excellence**

CCE/NPN	Members Served	Corresponding Data Center
Fire Department of the City of New York (FDNY; headquartered in Brooklyn with satellite centers at Brentwood, Fort Totten, Orange County, and Staten Island)	FDNY Responders	FDNY
1. Icahn School of Medicine at Mount Sinai 2. Northwell Health System (LIJ) 3. New York University, Bellevue Hospital Center (NYU) 4. State University of New York, Stony Brook (SUNY) 5. Environmental and Occupational Health Sciences Institute at Rutgers University (EOHSI)	All other Responders	Icahn School of Medicine at Mount Sinai (MSSM)
New York City Health + Hospitals (Bellevue Hospital Center, Gouverneur Healthcare Services, and Elmhurst Hospital Center)	Survivors	NYC HH
Logistics Health Incorporated (LHI)	NPN serves survivors and responders including the Pentagon/Shanksville, PA Responders	WTC Health Program

**C.1.3 Geographic Coverage**

Section 3306(8) of the Zadroga Act defines the New York Metropolitan Area to be covered by CCEs as:

An area, specified by the WTC Program Administrator, within which WTC responders and eligible WTC screening-eligible survivors who reside in such area are reasonably able to access monitoring and treatment benefits and initial health evaluation benefits under this title through a Clinical Center of Excellence described in subparagraphs (A), (B), or (C) of section 3305(b)(1).

Within the New York Metropolitan Area, the WTC Health Program will identify CCE contractors to maximize coverage to the member populations while minimizing overlap for administrative efficiency. Offerors shall identify the population and the geographic area to be covered in their proposal.

**C.2 Objective**

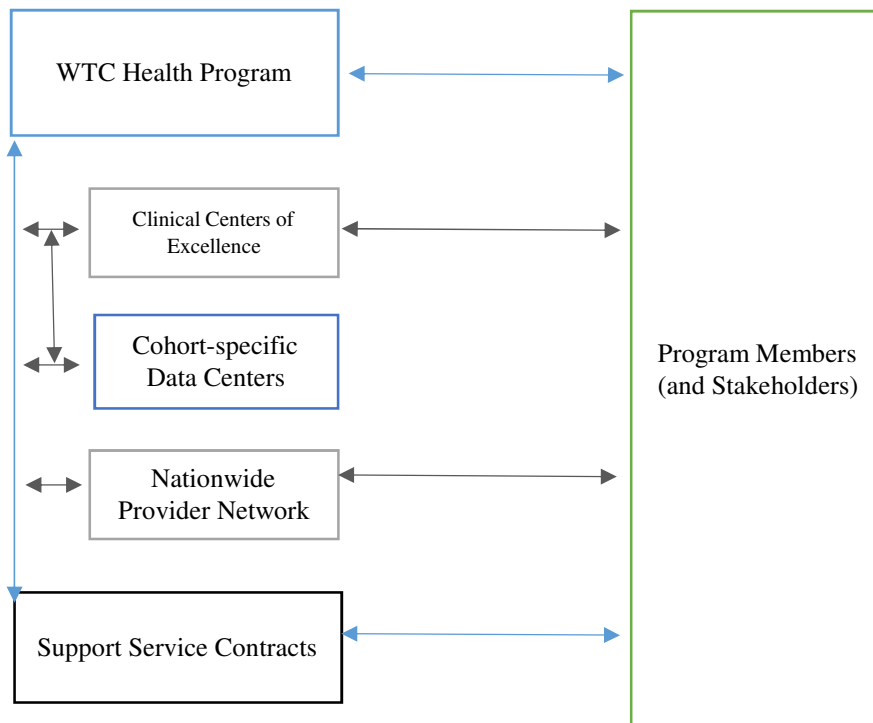
The objective of this requirement is to enter into a contract with multiple CCEs to provide services to the responders and survivors of the 9/11 attacks in a manner that is consistent with the requirements of the Zadroga Act. These requirements are provided in section C.3 Scope of Work of the PWS.

The Zadroga Act defines a CCE as “a Center that demonstrates to the satisfaction of the Administrator that the Center—(i) uses an integrated, centralized health care provider approach to create a comprehensive suite of health services under this title that are accessible to enrolled WTC responders, screening-eligible WTC survivors, or

certified-eligible WTC survivors; (ii) has experience in caring for WTC responders and screening-eligible WTC survivors or includes health care providers who have been trained pursuant to section 3313(c);<sup>2</sup> (iii) employs health care provider staff with expertise that includes, at a minimum, occupational medicine, environmental medicine, trauma-related psychiatry and psychology, and social benefits counseling; and (iv) meets such other requirements as specified by the Administrator.” Section 3305(b)(1)(A).<sup>3</sup>

The figure below shows a diagram of the components of the WTC Health Program that are relevant to this requirement. In addition, the Centers for Medicare & Medicaid Services (CMS) will receive claims validated by the WTC Health Program and process them through the U.S. Treasury to pay providers for services rendered.

Figure C.2.1 Components of the WTC Health Program



### C.3 Scope of Work

The Scope of Work for a Clinical Center of Excellence (CCE) is defined by the following requirements as specified in the Zadroga Act:

- (1) Providing initial health evaluation, annual medical monitoring, diagnostic, cancer screening and treatment benefits under Subtitle B of the Zadroga Act.
- (2) Ensuring that all CCE activities (i.e., benefits counseling, health education, health care service, case management, care coordination, specialty referral and authorization, and pharmacy prescribing and authorization) align with the WTC Health Program’s online Policy and Procedure Manual<sup>4</sup>.
- (3) Providing services to facilitate active participation to support retention of enrolled members.

<sup>2</sup> Section 3313 of the Zadroga Act addresses the national arrangement for benefits for eligible individuals outside New York, and subsection (c) relates to provision of training and technical assistance to healthcare providers participating in the network under subsection (a).

<sup>3</sup> The James Zadroga 9/11 Health and Compensation Act of 2010, as amended, can be found at:

<http://uscode.house.gov/view.xhtml?req=granuleid%3AUSC-prelim-title42-chapter6A-subchapter31&edition=prelim>

<sup>4</sup> The Program’s Policy and Procedure Manual (PPM) is subject to change and currently is maintained via the Program website for ease of access. The interested parties shall always consult with the PPM and WTC Health Program to obtain the latest information.

- (4) Providing case management and care coordination with participating provider network for health conditions covered by the WTC Health Program.
- (5) Providing member and provider counseling for program benefits with respect to the limited coverage model of the program, and coordination of care with community providers for health conditions not covered by the WTC Health Program (including pharmacy services and products).
- (6) Providing counseling for benefits for WTC-related health conditions that may be available under workers' compensation or other benefit programs for work-related injuries or illnesses, health insurance, disability insurance, or other insurance plans or through public or private social service agencies and assisting eligible individuals in applying for such benefits.
- (7) Providing translational and interpretive services and communication products for program participants who are not English language proficient.
- (8) Evaluating, documenting and ensuring that professionally recognized national and community practice standards are met for the quality of medical care provided.
- (9) Providing diagnostic and treatment referrals for conditions covered by the Program that appropriately inform and constrain the service authorization with the limited care model required by the Program.
- (10) Providing prescriber and member oversight activities to ensure appropriate use of pharmacy benefits as described by the Program's PPM (see footnote 4). This may include such things as mandatory use of generics, prospective authorization that documents medical necessity and retrospective pharmacy utilization review.
- (11) Reviewing/approving health care bills submitted by network providers to ensure alignment with Program requirements for medical necessity and prior authorization.
- (12) Establishing and maintaining a formal mechanism (i.e., active participation in Steering Committee meetings) for consulting with and receiving input from representatives of eligible populations receiving health care benefits under Subtitle B of the Zadroga Act from the CCE.
- (13) Coordinating monitoring, cancer screening, diagnostic and treatment benefits under Subtitle B of the Zadroga Act with routine medical care provided for the treatment of conditions other than conditions covered by a member's WTC Health Program benefit. This includes care coordination and case management where medical management decisions by non-participating providers may impact conditions managed by the CCE under the member's Program benefits.
- (14) Collecting and reporting to the corresponding Data Center (DC) data in accordance with Section 3304(b) of the Zadroga Act.<sup>5</sup>
- (15) Having in place safeguards against fraud, waste, and abuse that are satisfactory to the WTC Health Program Administrator, in consultation with the Inspector General of the Department of Health and Human Services.
- (16) Treating or referring for treatment all individuals who are enrolled WTC responders or certified-eligible WTC survivors at the CCE who present themselves for treatment of a WTC-related health condition and/or medically associated WTC-related health condition as certified by the WTC Health Program Administrator.
- (17) Having in place safeguards, consistent with Section 3304(d) of the Zadroga Act, to ensure the confidentiality of an individual's individually identifiable health information, including requiring that such information not be disclosed to the individual's employer without the authorization of the individual.

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<sup>5</sup> Section (F) refers to a requirement for the CCE, which the WTC Health Program has been able to facilitate the process more efficiently by providing claims data directly to the Data Centers without requiring the CCEs to do so.

- (18) Using amounts paid under Section 3305(c)(1) of the Zadroga Act only for costs incurred in carrying out the activities described in Section 3305(a), other than for the provision of monitoring and treatment benefits and initial health evaluation benefits under Subtitle B.
- (19) Using health care providers with occupational and environmental medicine expertise to conduct physical and psychiatric assessments or psychological experts to conduct mental health assessments, in accordance with protocols developed by a corresponding DC under 3305(a)(2)(A)(ii) through collaboration and guidance and approval by the WTC Health Program Administrator.
- (20) Conducting retention and outreach activities that align with the Program's strategic plan for retention and outreach, and are coordinated with the corresponding DC and the Program's designated staff liaison.<sup>6</sup>
- (21) Meeting all other applicable requirements of Title I of the Zadroga Act including regulations, policies and procedures (PPM)<sup>7</sup> designed to implement the WTC Health Program.

None of these services will be provided by CCEs for any person who has not been determined to be eligible for and enrolled in the WTC Health Program by the WTC Health Program Administrator. If someone contacts a CCE for services who has not been determined to be eligible and enrolled, the CCE shall instruct the person to contact the WTC Health Program Administrator about eligibility and enrollment.

The CCE shall ensure that the CCE's Operations Manual is aligned with the WTC Health Program PPM.

While there are no research activities conducted by a CCE under this contract, data collected will be used for analysis to improve clinical care, process and operational efficiency. The data from the monitoring and initial health evaluations and cancer screening will be transmitted to the corresponding Data Center to be used for program evaluation and research. In addition, the data from monitoring and initial health evaluations and cancer screening may be retained in an administrative data system for analytics intended to improve or evaluate operational and clinical activities. Neither the CCE nor the DC will be responsible for eligibility determinations. The eligibility determination and enrollment process will be handled by WTC Health Program.

### **C.3.1 CCE Contract Management**

The CCE contractor shall manage the contract to ensure that all subcontracts, staffing, reporting, security, deliverables, repositories, and Quality Assurance staff and services meet the requirements of the prime contract. The CCE contractor shall implement project management objectives that focus on monitoring, controlling, and balancing the project's three key constraints -- scope, budget, and schedule -- on an ongoing basis.

#### ***C.3.1.1 Project Management Plan***

The CCE contractor shall develop and implement a Project Management Plan (PMP) which shall define appropriate technical and financial project management over all tasks and deliverable documents in accordance with this PWS. The PMP shall establish the staffing and procedural framework for accomplishing the work required under this PWS. The PMP shall establish a transparent management baseline from which project monitoring and quality control is routinely conducted to verify adherence to the PMP. The CCE contractor's PMP shall include the proposed Staffing Plan with title, qualification, percentage of employment, numbers and duties of personnel who will be responsible for implementing the CCE Contract, including an identification of key personnel and management team with the percentage of their time to be devoted to the CCE Contract.

A draft CCE PMP shall be submitted with the offeror's proposal. A finalized CCE PMP shall be submitted to the WTC Health Program for approval within thirty (30) days of the contract award. Once approved, any changes to the PMP shall be updated as part of the monthly report and an updated PMP shall be submitted annually at the end of each contract year for the duration of the contract.

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<sup>6</sup> WTCHP Member Services Outreach and Education Plan

<sup>7</sup> The Program's Policy and Procedure Manual (PPM) is subject to change and currently is maintained via the Program website for ease of access. The interested parties shall always consult with the PPM and WTC Health Program to obtain the latest information.

### ***C.3.1.2 Operations Manual***

The CCE contractor shall develop and maintain an Operations Manual that contains a complete set of written Standard Operating Procedures (SOPs) which guide all contract-related services, processes, and activities. The SOPs shall be used to meet the objectives outlined in the PWS and provide the requisite security and process support for the WTC Health Program to include evidentiary documentation for formal Federal audits as well as Security Certification and Accreditation of contractor-provided systems for the program. The CCE Operations Manual shall be aligned with the Policy and Procedures Manual(s) for the WTC Health Program. The WTC Health Program Policy and Procedure Manual and Notices can be found at [http://www.cdc.gov/wtc/ppm\\_portal.html](http://www.cdc.gov/wtc/ppm_portal.html).

A draft CCE Contract Operations Manual shall be submitted with the Offeror's proposal. A finalized CCE Contract Operations Manual shall be submitted to the WTC Health Program for approval within sixty (60) days of contract award. Once approved, an updated CCE Contract Operations Manual shall be submitted, with changes indicated, to the WTC Health Program monthly for the entire duration of the contract.

### ***C.3.1.3 Communication Plan***

The CCE contractor shall develop and maintain a comprehensive Communications Plan that will enable it to deliver appropriate messages and communicate effectively to all identified stakeholders in a consistent and timely manner. The Communications Plan will identify all communication activities among the CCE contractor, the WTC Health Program (including participation in the weekly Medical Forum call attended by the Medical Directors, Administrators and WTC Health Program), the CCEs, the DCs, the Health Program Support (HPS) contractor, other contractors to the WTC Health Program, the WTC Health Program Steering Committees, and WTC Health Program members. A program management conference call will be held between the WTC Health Program and the CCE contractor to discuss requirements implementation and CCE operations relevant issues on a schedule to be agreed to by both the CCE and the COR.

In addition, the CCE shall respond to any written request from the WTC Health Program within a specified timeframe. A request is a written communication that specifies what is needed, why it is needed, and when it is needed, which may include the Change Request (CR). Requests may be preceded by oral communications. The CCE must acknowledge receipt of the request in writing and add the request to a tracking form and provide status update in the monthly report and/or the program management meeting; but not doing so still requires the contractor to respond by the deadline. If there are questions about the request that result in modifying the request or extending the deadline, an updated written request will be provided to the CCE.

The CCE contractor shall implement quality assurance measures to ensure communication process efficiency and compliance with federal privacy laws and regulations by testing any automated outputs to ensure accuracy of content and addressee before materials are delivered.

A draft CCE Contract Communications Plan shall be submitted to the WTC Health Program for review within sixty (60) days after contract award. The offeror will have two (2) weeks to submit a finalized plan upon receipt of comments from the WTC Health Program. Once approved, an updated Contract Communications Plan shall be submitted to the WTC Health Program, with changes indicated, monthly for the entire duration of the contract.

### ***C.3.1.4 Data Security and Continuity of Operations Plan***

The CCE contractor shall develop and maintain a comprehensive Data Security and Continuity of Operations Plan. The Data Security and Continuity of Operations Plan shall outline the CCE contractor's policies and procedures for ensuring data security, continuity of operations, and the transfer of data to the WTC Health Program. The data security and continuity of operations plan should follow standard FISMA, HIPAA and CDC guidelines. The Data Security and Continuity of Operations Plan shall follow the requirements of a certification and accreditation process and allow for continuous monitoring as outlined by CDC's Office of the Chief Information Officer (OCIO). A draft of the CCE Contract Data Security and Continuity of Operations Plan shall be submitted to the WTC Health Program for review within sixty (60) days of contract award.

As stipulated by **HHSAR 352.222-70**, the draft plan shall include identification of system of records and disposition. The system of record for this requirement is: Privacy Act System Notice 09-20-0147

- (a) Identify the system(s) of records and the design, development, or operation work the offeror is to perform and provide detailed description and point of contact (team or group) to the WTC Health Program;
- (b) Specify the disposition to be made of such records upon completion of contract performance. The offeror shall transfer all government records and all government furnished data within 30 days after the contract has ended or within the (to be) specified transition period. (Further details can be found in Attachment J-2, Information Technology Security and Privacy).

The offeror will have two (2) weeks to submit a finalized plan upon receipt of comments from the WTC Health Program. Once approved, an updated CCE Contract Data Security and Continuity of Operations Plan shall be submitted to the WTC Health Program, with changes indicated, monthly for the entire duration of the contract. (For further details, see Section C.3.8.3 for HIPAA and C.14 for FISMA compliance).

#### ***C.3.1.5 Risk Management Plan***

The CCE contractor shall prepare a Risk Management Plan in accordance with SEI (Software Engineering Institute) Risk Management Methods (or equivalent) and CDC/NIOSH/WTC Health Program policy for a continuous improvement approach to project performance. The Risk Management Plan shall include any potential program integrity risks and proposed strategies to reduce/mitigate these risks.

A draft CCE Contract Risk Management Plan shall be submitted to the WTC Health Program for review within sixty (60) days of contract award. The offeror will have two (2) weeks to submit a finalized plan upon receipt of comments from the WTC Health Program. Once approved, an updated CCE Contract Risk Management Plan shall be submitted to the WTC Health Program, with changes indicated, monthly for the entire duration of the contract.

#### ***C.3.1.6 Fraud, Waste, and Abuse Compliance Plan***

The CCE contractor shall prepare a Fraud, Waste and Abuse (FWA) Compliance Plan. As part of the FWA Compliance Plan, the CCE contractor shall designate executive and essential personnel to attend mandatory training in FWA detection, prevention, and reporting, and designate an officer or director in its organization with responsibility and authority for carrying out the provisions of the FWA Compliance Plan.

A draft CCE FWA Compliance Plan shall be submitted to the WTC Health Program for review within sixty (60) days of contract award. The offeror will have two (2) weeks to submit a finalized plan upon receipt of comments from the WTC Health Program. Once approved, an updated FWA Compliance Plan shall be submitted to the WTC Health Program, with changes indicated, monthly and open FWA issues shall be reported monthly for the entire duration of the contract.

#### ***C.3.1.7 Quality Assurance and Internal Audit Plan***

The CCE contractor shall prepare a Quality Assurance and Internal Audit Plan. A draft CCE Contract Quality Assurance and Internal Audit Plan shall be submitted with the Offeror's proposal. A finalized CCE Contract Quality Assurance and Internal Audit Plan shall be submitted to the WTC Health Program for approval within 60 days of the contract award. Once approved, an updated CCE Contract Quality Assurance and Internal Audit Plan shall be submitted to the WTC Health Program annually for the entire duration of the contract. If changes are made to the Quality Assurance and Internal Audit Plan, the changes shall be sent to the WTC Health Program within 30 days of the change. Updates to be provided monthly.

#### ***C.3.1.8 Cost Tracking and Invoicing***

The CCE contractor shall develop and manage budgets for all work to be performed. Budget development and management includes tracking and analysis of cost, Option Year budget development, and reporting budget-related issues to the COR and the Contracting Officer.

The CCE contractor shall develop, review, and submit monthly invoices which reflect adherence to budget/funding requirements. The invoice shall include a balance sheet.

The CCE contractor shall operate in a manner that is fully transparent, disclosing all sources of revenue and sharing all rebate dollars with the WTC Health Program based on a percentage approved by the WTC Health Program. The CCE contractor shall allow third parties to audit rebate payments and reconciliations.

The CCE contractor shall provide detailed line items and supporting documentation when other indirect costs, as defined by FAR Part 31, equal or exceed \$10,000.00.

#### ***C.3.1.9 Subcontracting***

The CCE contractor shall provide management and oversight of all subcontractors<sup>8</sup> as described in FAR Parts 42 and 44. This would include post-award conferences with subcontractors that involve the Contracting Officer and Contracting Officer's Representative.

The CCE contractor shall provide a draft subcontracting plan with their proposal to include all subcontracts the offeror intends to make prior to award. Post award, the offeror will have two (2) weeks to submit a finalized plan upon receipt of comments from the WTC Health Program. The plan shall require prior approval if any changes are made throughout contract performance. The CCE contractor shall manage any required subcontracts in a manner that best fulfills the requirements of the prime contract. The CCE contractor shall ensure its subcontractors and/or their agents who require the use of or access to individually identifiable information or protected health information under the provisions of this contract comply with WTC Health Program business associate agreements and federal law, policies and regulations, including FISMA, HIPAA, and CDC certification and authorization to operate requirements. The prime contractor will obtain a written assurance from each subcontractor to this effect. The CCE contractor shall notify the COR and CO in advance of placing any subcontract or modification, including the following information:

- (1) A description of the supplies or services to be subcontracted
- (2) Identification of the type of subcontract to be used.
- (3) Identification and selection of the proposed subcontractor.
- (4) A description of an oversight and quality assurance plan.

#### ***C.3.1.10 Change Control Process***

The CCE contractor shall manage the contract to ensure the required services are being performed and the required contract deliverables are being submitted. As part of this requirement, the CCE contractor shall maintain a WTC Health Program-approved change control process to identify, record, assess, and secure approval for changes to the project. The CCE contractor and the WTC Health Program will follow the CR protocol and use this process to classify, prioritize, approve, or reject changes, so that implementation does not negatively impact core mission applications, functions, or live production environments. Change requests need to be defined clearly, including their cost and schedule implications, to allow the WTC Health Program to make appropriate decisions. The CCE

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<sup>8</sup> Pursuant to FAR 44.101, Definitions, a "Contractor" means "the total contractor organization or a separate entity of it, such as an affiliate, division, or plant, that performs its own purchasing." A "Subcontractor" means "any supplier, distributor, vendor, or firm that furnishes supplies or services to or for a prime contractor or another subcontractor."

contractor shall receive prior authorization and approval of expenditures by the WTC Health Program before starting any work on changes. The CRs' status tracking must be reported in the monthly reports and any relevant issues or concerns must be discussed during the program management conference call with the COR.

#### ***C.3.1.11 Technical Experts Support***

The CCE contractor shall identify and provide an efficient multi- and inter-disciplinary team of personnel at all operational levels with advanced technical expertise, health service experience and appropriate skills set to perform services required.

The CCE contractor's multi- and inter-disciplinary team shall include, at the minimum, medical (physical and mental) and nursing professionals, licensed case managers and social workers, , health service administration manager and other needed staff to support program management and operations (i.e., quality assurance, provider network, analytics, coding and claims). The CCE contractor shall provide a well-defined and cost-effective mix of specialists in Federal Health Care Delivery Policies and Procedures, Federal Health Care Pharmacy Delivery Policies and Procedures, Case Management, Federal Health Information Technology, Federal Legislative/Regulatory Affairs as pertains to pharmacy benefits and benefit design, and Provider Education/Relations, Risk and Health Communication and show how these specialists align to Program requirements. The CCE contractor shall have exceptional expertise in standing up and operating a high-visibility federal healthcare program that requires exceptional end-user responsiveness.

The CCE contractor and its staff should be very familiar with the Zadroga Act and other related federal health laws and regulations and maintain the knowledge and skills needed to administer a federal healthcare program.

#### ***C.3.1.12 Program Improvement***

The CCE contractor shall work with the WTC Health Program to facilitate and develop ongoing program improvements that address the CCE needs of the WTC Health Program, members, the CCEs, the DCs, the HPS contractor, and other stakeholders. The CCE contractor must address all required mandates of the Zadroga Act and incorporate new innovations, and new means of providing superior care and service delivery to program participants and stakeholders. The CCE contractor shall also be mindful of the WTC Health Program's need to be responsive to Congress and other governmental organizations and provide the means for ensuring the kind of program transparency that will demonstrate the CCE contractor is meeting program needs while containing costs and reducing program operational risks. The CCE contractor shall work closely with the WTC Health Program to fulfill program integrity and research requirements and make recommendations to address critical Fraud, Waste, and Abuse initiatives. This includes regularly reporting to the WTC Health Program both research and reports on potential cost-saving measures.

A qualified team of medical professionals and program managers should research and review potential cost-saving initiatives, and provide evidence-based recommendations to the WTC Health Program pharmacy team regarding formulary requirements and drug inclusion into the formulary. The CCE contractor shall incorporate inferential data or statistics as part of measures for program improvement, quality assurance, and fraud, waste, and abuse detection.

A draft CCE Program Improvement Plan shall be submitted to the WTC Health Program for review within sixty (60) days of contract award. The offeror will have two (2) weeks to submit a finalized plan upon receipt of comments from the WTC Health Program. Once approved, an updated CCE Program Improvement Plan shall be submitted to the WTC Health Program, with changes indicated, monthly for the entire duration of the contract.

#### ***C.3.1.13 Reporting (Part of administrative function)***

The CCE contractor shall provide communications and reports to the WTC Health Program on the ongoing CCE Contract implementation status as well as status reports documenting program progress and risks related to program management and administration, including critical-success-factors and key-performance-indicators. In addition to the monthly updates of the Project Management Plan, the CCE contractor shall submit accurate and detailed monthly, quarterly, bi-annual and annual reports as required by this PWS.

### C.3.2 Monitoring and Initial Health Evaluations

The CCE shall provide a baseline for new enrollees and follow-up examinations to all members. The purpose of the monitoring exams is to: (1) provide a periodic physical and mental health assessment designed to identify acute and latent health effects that are WTC-related; (2) serve as an avenue for clinical data collection, analysis and reporting to ensure that all services provided adhere to the appropriate periodic monitoring and initial health evaluation protocols; and (3) inform the diagnosis of WTC-related health conditions that could lead to a program-covered treatment referral.

A baseline (initial) exam includes a medical history questionnaire (occupational history, clinical history, and review of symptoms), an exposure assessment, vital signs assessment, spirometry testing, blood and urine analyses, a chest radiograph if clinically indicated, and a physical examination. Annual follow-up monitoring examinations include the same components with the exception of the exposure assessment and the chest radiograph. Chest radiography may be conducted when indicated but not more often than every two years, unless the monitoring exam indicates otherwise. If a test result indicates the presence of a WTC-related condition, or is inconclusive, the monitoring physician will refer the member for additional diagnostic testing and/or treatment. The monitoring examinations shall be conducted by a qualified physician, preferably one specializing in Occupational Medicine.

The method outlined below is an example of how monitoring services may be delivered.

**Example:**

*The Medical History Questionnaire (MHQ), which is comprised of standardized assessment instruments for multiple physical and mental health conditions, may be conducted by a Registered Nurse, Licensed Practical Nurse (LPN), physician's assistant (PA), or physician who has been trained to use the MHQ. The MHQ typically takes 45 minutes to complete. The work-up testing includes spirometry (i.e., pulmonary function test or PFT), chest radiograph (if required), and blood and urine assays.*

*Next a summary report is prepared for the monitoring physician. The summary report contains information from the MHQ and the work-up appointments (results from the laboratory tests, chest radiography and spirometry) plus a summary of past medical records. To complete the monitoring examination, the monitoring physician reviews the summary report, conducts a clinical interview and a physical examination, and synthesizes the clinical information for discussion of findings and treatment referrals with the program participant. The CCE shall ensure that the monitoring physician has a copy of the MHQ summary report in time to review it before conducting the member's clinical examination. The CCE shall be responsible for scheduling all components of the medical monitoring process.*

For responders, periodic medical monitoring is conducted annually. If the medical monitoring exam reveals an illness that is on the list of WTC-related health conditions and the physician determines that the condition meets the criteria for a WTC-related health condition, the physician shall transmit his determination to the WTC Health Program Administrator for certification. The CCE Director will provide clinical and administrative oversight for adherence to monitoring protocols, including the need for additional medical testing to confirm a diagnosis of a newly detected WTC-related health condition and/or a health condition medically associated with a given certified WTC-related health condition. The CCE will assist the member in scheduling appointments to obtain additional diagnostic evaluation as needed. Medical management of qualifying health conditions will be covered in Section 3.3 (Cancer Screening, Diagnostic and Treatment Services).

As a part of the medical monitoring evaluation process, the CCE shall accomplish the following tasks:

- Scheduling the exam for the member with a provider in the CCE
- Summarizing prior medical records and ensuring that the medical monitoring exam physician has a copy of the summary report prior to the scheduled physical exam appointment
- Conducting the Medical History Questionnaire interview
- Performing the required lab work and a chest radiograph (if indicated)
- Performing the pulmonary function testing (PFTs)

- Ensuring that the medical monitoring physician has a summary of the Medical History Questionnaire interview, a summary of the prior treatment records, if available, and the prior medical monitoring exam records in time for the scheduled physical exam
- Reporting the results of the medical monitoring examination to the member
- Ensuring that medical monitoring examinations are coded correctly and that claims are submitted promptly, including Coordination of Benefits (COB) process, if appropriate
- Collect primary insurance information for pharmacy benefits and submit that information to the appropriate entity to ensure coordination of benefits of pharmacy claims when appropriate.
- Coordinating medical testing or subspecialty evaluation for further diagnosis of suspected WTC-related health conditions with the CCE Director
- Submitting physician determinations of WTC-related health conditions or health conditions medically associated with a given WTC-related health condition to the WTC Health Program Administrator for certification
- Following appropriate authorization channels for treatment services (including medications) and coordinating referrals for treatment of qualifying conditions
- Explaining the monitoring and treatment benefits that are provided under the WTC Health Program, as well as that no treatment benefits are provided under the WTC Health Program for non-qualifying conditions
- Providing WTC Health Program Benefits Counseling
- Providing Social Services referrals
- Performing quality assurance checks on the medical monitoring process and the appropriateness and completeness of the medical records
- Reviewing and approving all claims related to monitoring and initial health evaluations and preparing claims for processing and payment, including COB for survivor population when applicable, as directed by the WTC Health Program Administrator
- Reviewing and transmitting to the DC, data from the Monitoring and Initial Health Evaluations to be used for research and analysis, as depicted in Figure C.3.2.1. For instance, this would include data on the number of exams conducted, people screened, and referred for treatment, and other such data as requested by the WTC Health Program Administrator.
- Community referral for conditions detected that are not eligible for treatment under the WTC Health Program benefit.
- Documenting the certification(s), prior authorizations for services (including medications), home visits and benefits counseling in a member-specific and auditable record.
- Coordinating care for conditions that the WTC Health Program covers using an integrated case management plan for members with complex diseases.

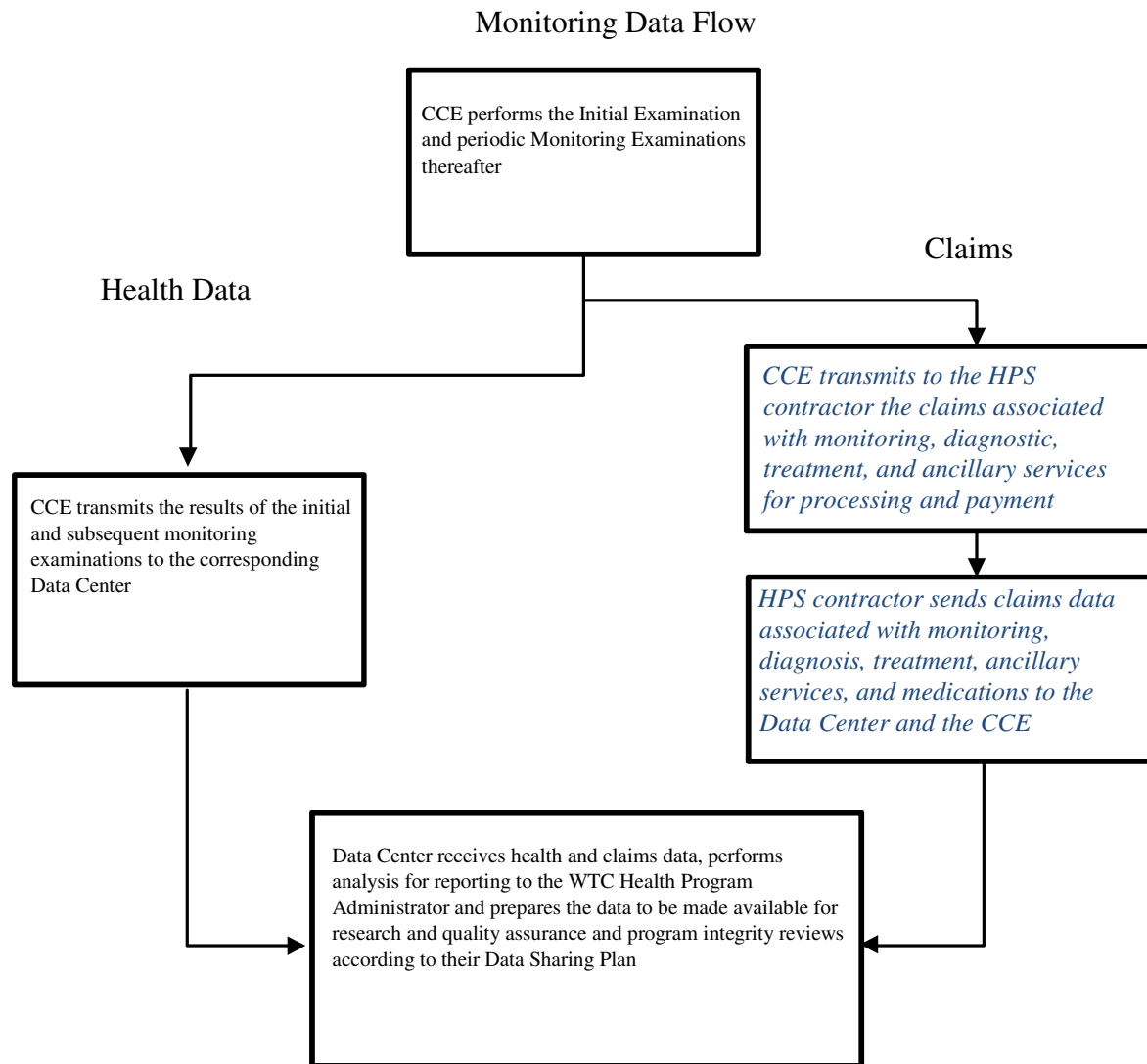


Figure C.3.2.1 Data flow related to monitoring examinations.

In addition, the CCE shall develop and implement procedures to handle emergency situations or manage crises that may arise during monitoring, treatment, case management, or other member interaction. The CCE shall educate and train their staff and network providers in the proper completion of paperwork, the limitations of coverage, protocol changes, and benefits counseling and shall disseminate scientific information regarding WTC exposures and related health outcomes.

When a medical monitoring exam has been completed by a provider in the CCE, the CCE shall ensure that all completed medical monitoring records are maintained by the CCE. The CCE shall be responsible for providing a letter to the member informing them of the exam results within 15 business days of the completion of the exam.

Following a medical monitoring exam and based on direction from the WTC Health Program Administrator, the CCE shall submit a CMS1500 Form (or similar form) for reimbursement. These data shall be submitted electronically and shall, at a minimum, contain all of the data required by the CMS1500 Form. The CCEs shall have adequate financial systems for the timely submission of claims.

The CCE shall develop protocols or procedures for the following medical monitoring exam-related issues, working in conjunction with their respective DC and incorporate existing requirements of the Program. These protocols or procedures shall be submitted to the WTC Health Program Administrator for approval as a part of the CCE Operations Manual;

- Obtaining relevant medical records for individuals previously served by a CCE
- Monitoring examination protocols including quality assurance components which are built upon knowledge of accepted practice guidelines
- Scheduling medical monitoring exams
- Monitoring examination delivery of service methodology
- Ensuring that the proper data are sent to the DC from a medical monitoring exam conducted by the CCE
- Ensuring that a letter is sent to the member informing them of the exam results within two weeks of the completion of the monitoring exam
- Processing and submitting claims for all medical monitoring exam-related services
- Collecting and maintaining all records required for project management and reporting.

### **C.3.3 Cancer Screening, Diagnostic and Treatment Services**

The CCE contractor shall develop and implement procedures to provide cancer screening evaluations for lung, colon, breast, and cervical cancers following the U.S. Preventive Services Task Force recommendations. The WTC Health Program PPM indicates which members are eligible for cancer screening. Testing included as part of the cancer screenings within program benefits can be obtained from the Program's codebook and treatment plans. This information must be incorporated into the CCE Operations Manual, as well as information regarding CCE procedures for member outreach to notify members of screening eligibility, documentation of service offerings, services delivered and notification of results, and treatment referral when needed.

As required by the Zadroga Act and the Program's regulations at 42 C.F.R. pt. 88, the WTC Health Program Administrator shall reimburse costs for medical treatment for WTC-related health conditions at rates no higher than the Federal Employees Compensation Act (FECA) pricing for an outpatient facility and no higher than FECA or Diagnostic Related Group (DRG) pricing for an inpatient facility (DRG pricing is used by CMS to establish Medicare fee-for-service rates), or other rates established pursuant to the Act and regulation. Information on the Division of Federal Employees' Compensation of the OWCP can be found at: <http://www.dol.gov/owcp/dfec/>.

Diagnostic and treatment services for members shall be provided through the CCE network of credentialed providers or through WTC Health Program providers (when available).

As per the Zadroga Act, all treatment services must be in compliance with an established standard for medical necessity and program clinical guidelines. Examples of program treatment guidelines are contained in WTC Health Program policy guidance (which can be found online at [http://www.cdc.gov/wtc/ppm\\_portal.html](http://www.cdc.gov/wtc/ppm_portal.html)). The CCE Director shall ensure that all diagnostic and treatment services comprise reasonable and appropriate care based on medical necessity principles, evidence-based practice, scientific evidence, professional standards of care, expert opinion or other relevant information and that has been included in the medical treatment protocols approved by the WTC Health Program Administrator. All treatment services will be billed on a fee-for-service basis. The CCE contractor may rely upon the WTC Health Program code book for pre-approved allowable services and procedures for all diagnostic work-ups, initial health evaluations, medical monitoring, cancer screening, and treatment services. The fee schedule will be the same as those published by the Office of Workers' Compensation Programs (OWCP), U.S. Department of Labor, which are in compliance with the Federal Employees Compensation Act (FECA) and/or payment rates designated by the WTC Health Program Administrator.

Information on the Division of Federal Employees' Compensation of the OWCP can be found at: <http://www.dol.gov/owcp/dfec/>. Figure C.3.3.1 shows the data flow related to treatment services.

## Treatment Data Flow

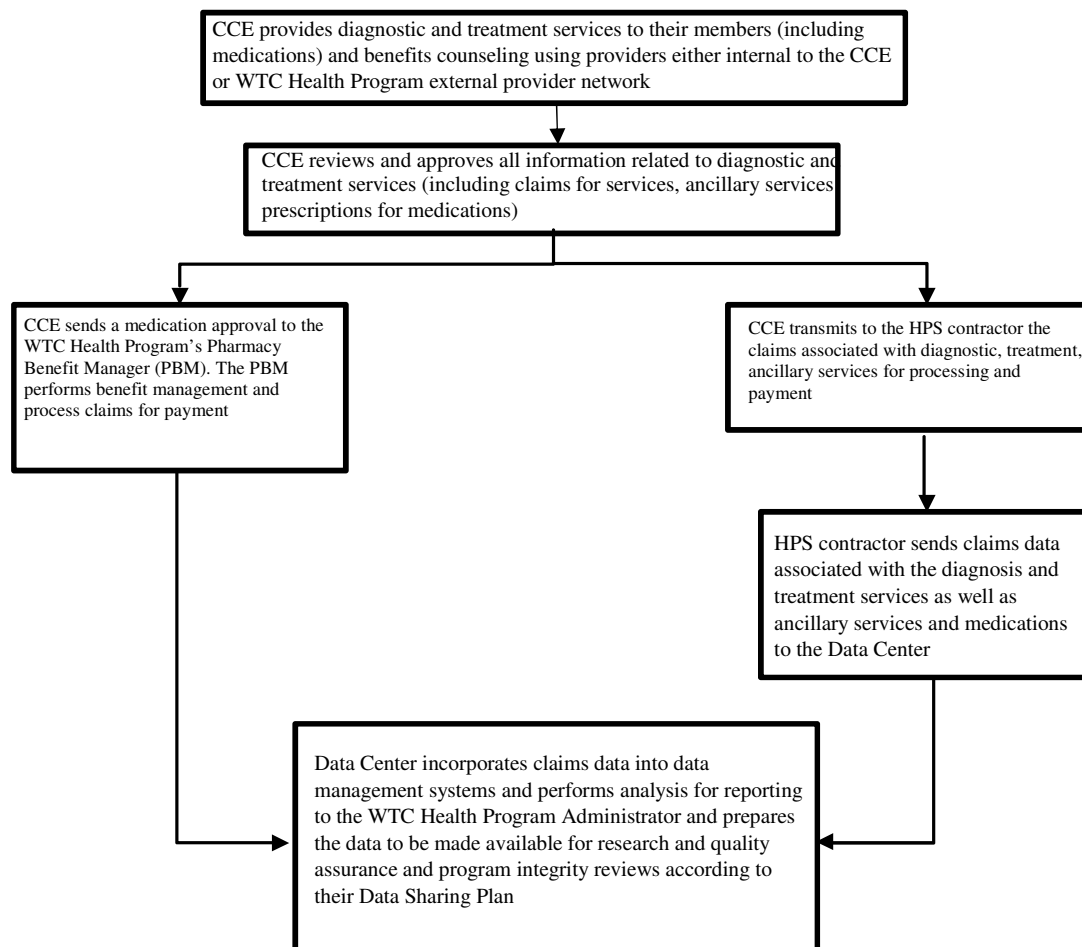


Figure C.3.3.1 Data flow related to treatment services

The CCE Director will provide clinical and administrative oversight for all diagnostic and treatment services (including medications) provided for a member's certified health conditions. Pending certification of a member's health condition, the CCE Director shall comply with program requirements regarding "authorization of treatment pending certification" (see PPM citation: Chapter 4, section 7 at <http://www.cdc.gov/wtc/ppm.html#4g>). Upon authorization, the CCE shall be responsible for providing appropriate treatment services or referrals, which will be scheduled by the CCE. The CCE shall assign a qualified provider within the CCE or their external provider network. The CCE shall ensure that all treatment providers are knowledgeable about the specific health conditions, procedures, and medications covered by the WTC Health Program and appropriate procedures for handling non-covered health conditions, medical emergencies and program treatment appeals. In addition, the CCE shall ensure that only treatments for WTC-related health conditions and medically associated health conditions are billed to the WTC Health Program. The CCE shall also ensure that appropriate staff are properly trained in providing benefits counseling.

In addition, the CCE shall have the capability for a medical records locator and other case management tools. This function will facilitate the retrieval of all medical records from any provider for any member within the CCE or their external provider network. Any required data to be used for research shall be reviewed, approved, and transmitted to the corresponding DC.

The CCE shall develop procedures for the following treatment-related issues; these procedures shall be submitted to the WTC Health Program Administrator for approval as a part of the CCE Operations Manual:

- Training of providers who will perform treatment services
- Treatment protocols which include health care Quality Assurance provisions for benchmarking protocol adherence and identifying key performance indicators for quality improvement activities (Collaborating with WTC Health Program and DC)
- Coordinating authorization, referral and service delivery for additional medical testing or specialty evaluation to confirm the diagnosis of qualifying conditions
- Requesting authorization to treat and submitting physician determinations of a member's qualifying conditions for certification by the WTC Program Health Administrator
- Coordinating services for treatment (including medications) of qualifying conditions
- Explaining benefits, including guidance to providers and participating members regarding referrals and services for non-covered conditions and providing benefits counseling
- Informing and assisting members with the secondary review process when certification or treatment is denied and/or with the
- Approval and utilization review for non-emergency inpatient services (i.e., overnight stay), and notification within 48 hours of emergency hospitalization for WTC-related health conditions and medically associated conditions. All approvals shall be done in accordance with the Program's Policy and Procedures Manual (PPM). The CCE must maintain all prior authorization records and update members' medical records accordingly. ([Refer to PPM Chapter 4 Medical Benefits Section 15 Inpatient Hospitalization](#))
- Coding, claims processing (including COB), and submission of claims, as directed by the WTC Health Program Administrator, for all diagnostic and treatment-related visits and services covered under the WTC Health Program
- Criteria and protocol to engage emergency services for medical and behavioral health crises (including limitations of program cost coverage).

In all cases, WTC Health Program policy guidance defines the scope of healthcare coverage of the WTC Health Program including the WTC Health Program Code Book, which is being updated frequently

The WTC Code Book (subject to change as needed) contents include:

A list of approved health conditions by disease classification found in the International Classification of Diseases, 10<sup>th</sup> edition (WHO) under the following categories: upper respiratory, lower respiratory, gastrointestinal, musculoskeletal, mental health, cancer, and updates are being made for acute traumatic injury. Each category is further subdivided into tables based on pertinent but non-specific findings needing further diagnostic work-up, conditions that have been associated with WTC exposures, and conditions that are medically associated with the WTC-related health conditions in that category. While all of these conditions would be subject to health surveillance efforts, additional conditions are of interest to track in the program and are captured in a separate table that would contribute to future program decision-making.

- WTC-approved treatment procedures (CPT and HCPCS)
- A list of approved Durable Medical Equipment
- Approved Formulary

### **C.3.4 Healthcare Provider Network**

The CCE shall participate in the WTC Health Program Provider Network for external providers and prescribers, and establish and maintain an adequate internal health care provider network to serve all members who are assigned to the CCE. The WTC Health Program Provider Network may include, but not be limited to, hospitals, specialty clinics, trauma centers, specialists, and primary care physicians, in sufficient numbers, adequate coverage for services and at convenient locations for the members. The internal healthcare provider network shall be within the CCE institution and the CCE shall actively participate in the WTC Health Program Provider Network and, as allowed, the shared providers list created through the NPN's Provider Network, which are all part of the WTC Health Program's credentialed and enrolled provider networks that will be maintained by the HPS contractor. CCE internal providers are not automatically registered in the shared provider list.

The physicians who will be conducting the medical monitoring assessments and physical examinations shall be experienced in practicing occupational medicine, internal medicine or family medicine (e.g., conducting occupational health screening and medical surveillance); preferably board-certified specialists. The CCE shall develop training to properly instruct the participating internal CCE providers about the potential exposures and health outcomes that have been associated with the WTC attack and the conditions and services covered by the WTC Health Program.

The CCE contractor shall be responsible for ensuring that the internal CCE health care providers who provide diagnostic and treatment services meet all requirements of the CCE contract, and are credentialed according to WTC Health Program standards, currently the National Committee for Quality Assurance (NCQA) Standards.

The CCE shall be responsible for ensuring that the internal health care providers who provide diagnostic and treatment services meet all requirements of the CCE contract including complying with all requirements for Workers' Compensation filing.

#### ***C.3.4.1 Licensing and Insurance***

The CCE shall ensure that all internal providers are properly licensed under applicable state laws and/or regulations and are properly insured with at least minimum amounts of malpractice insurance as required by the provider's State licensing requirements. Licensing and insurance documentation for each provider shall be reviewed by the CCE contractor and a notice sent to providers one month prior to any expiration of the license or the insurance policy term to confirm renewal. The CCE contractor shall report to the WTC Health Program on a quarterly basis, the number of providers that were reviewed and found to be properly licensed and insured. The CCE's Operations Manual shall provide the details of establishing and credentialing their provider network according to their internal institution's protocol and align with the WTC Health Program's provider network management protocol through the HPS contractor.

#### ***C.3.4.2 Training***

The CCE shall ensure that all providers and other personnel who perform work under the CCE's contract are properly trained to perform their function. This includes initial and ongoing training.

For internal providers and prescribers, the CCE shall coordinate with the HPS contractor who will provide a standardized training package that will be updated on a regular basis for the CCE to implement and maintain their own internal training that shall also meet the standard of their own institution. In addition, the internal providers and prescribers shall consider taking the educational modules produced by the WTC Health Program. The modules explain details of the WTC Health Program, as well as provide clinical information for screening and treating patients who may have been exposed to the 9/11 attack sites.<sup>9</sup>

For external providers and prescribers, the CCE shall coordinate with the HPS contractor who will provide a standardized training curriculum including, but not limited to, all WTC Health Program available courses through MedScape.

The CCE's Operations Manual shall provide the details of establishing, credentialing and maintaining internal providers and prescribers and coordination with the HPS contractor on training of all providers and prescribers.

### **C.3.5 Claims Submission and Payment**

All providers in the CCE shall submit claims and receive payment according to the following process:

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<sup>9</sup> <http://www.medscape.org/viewcollection/33376> this link may be changed to the CDC's external site by the end of 2016.

Following completion of a medical service, all providers (internal and external to a CCE) will submit appropriate electronic claims (CMS1500 or UB-04) that are in compliance with the ANSI 5010 Standard and as instructed by the WTC Health Program (exceptions may be allowed to submit paper claims with prior approval). Claims from external providers providing care for a member assigned to the CCE must be reviewed and approved or denied by the appropriate CCE through a mechanism established by the WTC Health Program to post submitted claims. Such actions must be completed within one week of external provider claims being posted for review. The CCE shall describe the specific methodology by which the review will be conducted, and that methodology will be consistent with the treatment protocols pre-authorized by the CCE and standards of care for the certified health conditions. The CCE shall have an adequate financial system for the submission of internal claims within the timely filing limits and performance standards established by the WTC Health Program which includes 95% of all internal services to be submitted as clean claims within 30 days of the dates of service.

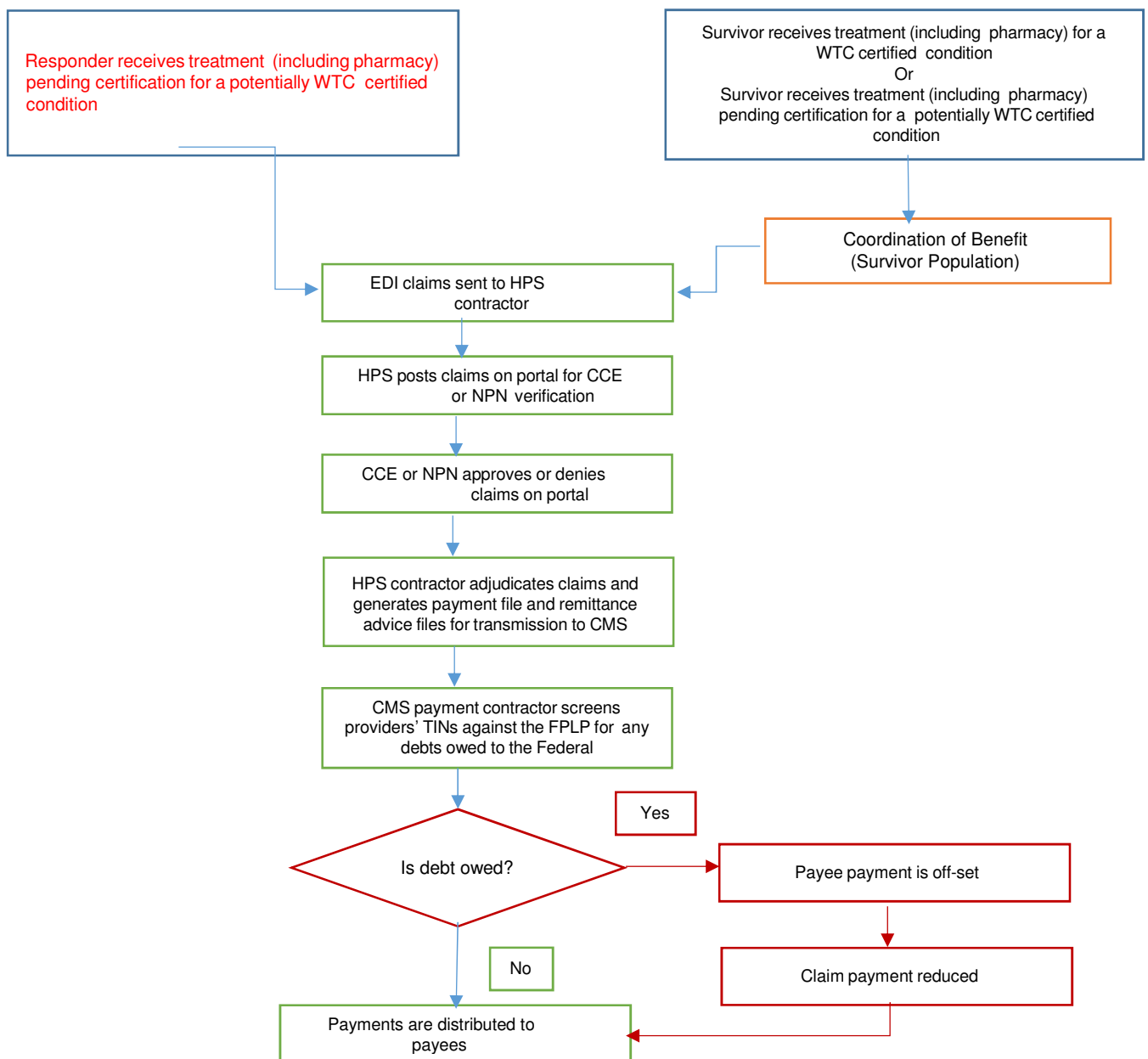
All providers must be registered with the WTC Health Program prior to service being rendered. CCEs may request that new providers be added to the WTC Health Program Provider Network through a process defined by the WTC Health Program.

The WTC HPS contractor will validate that the claims are in the standard 837 format for electronic processing, adjudicate the claims based on HIPAA Standards and WTC Health Program rules, re-price the claims to no more than the FECA rates for professional claims and DRG pricing for institutional claims as followed by Medicare, and submit the approved and denied claims to the CMS contractor for payment of approved claims. The CMS payment contractor screens all payees TINs against the Federal Payment Levy Program (FPLP) for any debts owed the Federal Government. Where there is a match between the providers' TINs and the FPLP, payments are levied to satisfy the debts owed the Federal government. The levied amount may be for the full payment amount or for a percentage of the amount owed. The WTC Health Program remittance advice (standard 835 format) will reflect the amount levied and the reason for the levy (P.L. 105-34 – Taxpayer Relief Act of 1997 and Internal Revenue Code Section 6331(h) provides CMS authority to collect overdue taxes through a continuous levy on certain federal payments; this includes Medicare FFS payments).

The CCE contractor shall perform coordination of benefits (COB) with other health plans, as applicable, for survivors who are eligible to receive health care services. Any costs or items not reimbursed by such health plan, due to the application of deductibles, copayments, coinsurance, other cost sharing, or otherwise, are reimbursable to the CCE to the extent they are covered by the WTC Health Program.

The CCE's Operations Manual shall provide the details of the planned COB process that is consistent with requirements of the WTC Health Program, the ACA and applicable laws.

Figure C.3.5.1 Claims Submission and Processing



### **C.3.6 Pharmacy Benefit Management**

The CCE contractor shall work closely with the WTC Health Program PBM to provide pharmacy benefits to WTC Health Program members. Further guidance on the PBM functions and coordination with the CCE and other contractors in the program will be provided upon the selection of the PBM contractor and WTC Health Program Administrator's decision.

The CCE contractor shall refer to the WTC Health Program for latest guidance and routinely review the WTC Health Program's Policy and Procedures Manual for updates at <http://www.cdc.gov/wtc/ppm.html>.

The CCE's Operations Manual shall reflect the current protocols of the WTC Health Program including the management of the pharmacy benefits for enrolled members.

The CCE shall ensure that all prescriptions issued to enrolled members are for WTC-certified health conditions, or medically associated conditions, in compliance with the Zadroga Act and the PPM. Medical necessity shall be documented for all treatments provided by the WTC Health Program, including prescriptions. All pharmacy decisions must be made by a practicing clinician with appropriate knowledge of the medication being prescribed, the Member's certified condition, and their treatment plan.

#### **Member Education:**

The CCE contractor shall ensure all members enrolled with their program are informed and possess an in-depth understanding of their pharmacy benefits through the WTC Health Program. The CCE's shall also provide Members with notice when Program changes may occur that affect their pharmacy benefits.

#### **Covered Medications and Restrictions:**

The WTC Health Program reserves the right to put restrictions in place on medications when necessary to ensure prescriptions issued through the WTC Health Program comply with program policy. The WTC Health Program, in conjunction with the PBM, will develop and update a formulary that will detail covered medications within the program as well as criteria that must be met prior to the prescription being approved through the Program. The CCE shall have protocols in place to ensure compliance with any medication restrictions and requirements described in the formulary and the PPM for prescription drugs.

#### **Restrictions may include, but are not limited to:**

- Eligibility requirements such as enrollment, treatment plan, and/or certified conditions through the Program.
- Prescriber enrollment.
- Specialty, mail-order, or retail requirements for certain medications.
- [Edits at the point of sale](#) such as drug utilization reviews (therapeutic duplication, high dose, drug interaction, etc.), refill too soon, days' supply limitations, excessive quantity dispensed, high dollar medications, prior authorization required, etc.
- Step therapy (preferred and non-preferred medications).
- Covered formulary medications.
- Non-formulary medication approval processes and criteria.
- Prescribing criteria.

#### **Reports:**

The CCE shall review data, reports, and clinical documentation provided by the PBM or other data systems, to analyze prescribing trends and practices of their physicians and members. This information shall be used to determine cost savings opportunities, inappropriate prescribing trends, compliance with benchmarks set by the program, and to provide relevant conclusions on their population health status and outcomes. Such reports may include, but are not limited to:

- Percentage of generic medications vs. brand name medications filled.
- Analysis of controlled substance use.
- Individual prescriber analysis.
- Preferred vs. non-preferred medications filled.

### **Compliance with State and Federal Law**

- All prescriptions issued to Members within the WTC Health Program shall be written and dispensed in compliance with federal prescribing laws and the state's prescribing laws where the CCE is licensed.
- Prescribers must reference the state's PDMP (if available) prior to prescribing a controlled substance.

### **Retrospective Reviews:**

Please refer to the PPM to determine if and what retrospective reviews may be required of the CCE. CCE's must ensure that staff are able to perform retrospective reviews within the time intervals stated in the PPM (i.e., weekly, monthly, etc.).

There must be medical necessity documented for all prescriptions reviewed retrospectively and they must meet all requirements stated in the formulary and PPM and other related technical guidance. If a medication is found to be inappropriately filled through the WTC Health Program by the CCE, the CCE shall ensure that the Program is notified in accordance with procedures stated in the PPM and technical guidance to ensure future fills of that medication will no longer be billed to the WTC Health Program. The cost of inappropriate prescriptions filled through the Program due to the CCE neglecting to follow these policies and procedures shall be recouped by the WTC Health Program from the CCE's funding. The CCE is required to include retroactive reviews findings in the quarterly report.

### **C.3.7 Member Services**

The CCE shall develop procedures for providing the following Member Services. These procedures shall be submitted to the WTC Health Program Administrator for approval as a part of the CCE Operations Manual.

#### **C.3.7.1 Member Retention**

The CCE contractor shall be responsible for member retention. Member retention activities are those activities performed to maintain contact with members and to encourage inactive members to participate in the Program. On an annual basis, the CCE contractor shall make multiple attempts to update contact information for all members. Appropriate contact methods include mailings, telephone calls, and emails. Contact attempts must be initiated no later than 12 months after the last recorded update and include a minimum of 3 calls in two weeks, a call and a letter or postcard at the end of month 1, in the middle of month 2, and at the end of month 2. The CCE Operations Manuals shall provide details of their planned member retention process which is due within 3 months after award of the contracts and must be approved by the WTC Health Program.

The benchmark for an acceptable retention rate is where at least 65% of members have had their last exam within 27 months prior to the end of each fiscal quarter (or within 6 months of the date of enrollment for new members) and are not in any of the following categories: (1) deceased; (2) stated that they do not want to participate in any aspect of the Program and not to contact them again; (3) no valid contact information is available, so the member cannot be reached. Furthermore, when the rate of retention is greater than 65%, the benchmark for change in retention rate is no decline greater than 1% in a quarter or greater than 0.5% in a year.

Each quarter, the CCE contractor will report the number of members who have updated contact information within the 12-month period ending at the previous quarter. As an example, for the 12-month period ending on March 31, 2017, the June 30, 2017, report will give the number of members with updated contact information on or after April 1, 2017. All members will be accounted for in at least one of the three categories above, that their contact information has been verified/updated, that there was no response from the member, or that the required effort to contact the member was not made. There will be no more than 0.5% of members for whom the required annual contacting effort was not made.

The CCE's Operations Manual shall provide the details of the member retention process and activities, which should be reported in the quarterly report.

### ***C.3.7.2 Information and Education***

The CCE shall be responsible for providing information and education to potentially eligible Responders or Survivors to make them aware of the WTC Health Program and to encourage these potential members to have their eligibility determined. The CCE shall conduct activities for communicating with potential members and interact with the corresponding DC and the WTC Health Program Administrator in providing these services. Types of information and education services should include:

- Answering general questions in regard to program eligibility processes
- Collaborating with the appropriate DC and other corresponding CCEs in maintaining a website to provide WTC Health Program information for the members who are being served. The website shall be Section 508 compliant and be updated at least monthly.
- Explaining the member's rights and responsibilities as a member of the WTC Health Program.
- Collaborating with the appropriate DC and other corresponding CCEs in providing program information updates to members and providers (i.e., newsletters, letters, brochures, email)
- Explaining the process for obtaining WTC Health Program services
- Providing information on the providers from whom WTC Health Program members may obtain services
- Fielding and responding to member questions and complaints received regarding the WTC Health Program benefits and/or services (i.e., captured from member satisfaction survey, a resource line, or Case Managers)
- Advising members of the available appeals process and the member's rights to a secondary review.

The CCE's Operations Manual shall provide the details of the Information and Education Program.

### ***C.3.7.3 Program Benefits Counseling***

The CCE shall be responsible for providing program benefits counseling. Program benefits counseling shall include explaining the benefits and covered services offered under the WTC Health Program, including WTC-related health conditions and medically associated WTC-related health conditions and limitations, and any conditions associated with the receipt or use of benefits. This service occurs through social workers, case managers, member service coordinators, peer counselors, or patient care coordinators. A member may be referred to a benefits counselor (case manager) after a monitoring visit if he/she responded "yes" to needing additional information or assistance with social services on the Medical History Questionnaire. A referral may also occur if a member calls the CCE contractor at any time about such services. The Program will also require a benefits counselor to reach out to all members on a periodic basis to assess benefits counseling needs. This may be through phone, postal mail, or email. The case manager will assess the needs of the patient and will provide information and contacts specific to the member's needs for connecting with agencies or systems that exist outside of the WTC Health Program.

#### **Benefits counseling is defined as:**

A WTC Health Program service provided by a benefits counselor, social worker, or other designated staff person, who helps a member to identify the benefits he or she may be eligible for and explains how to apply for those benefits. Benefits counselors also refer members to external benefits experts as needed to help the member access benefits.

There are 7 categories of benefits counseling that should be made available through the CCE:

1. WTC Health Program Benefits Counseling
2. Worker's Compensation Counseling
3. September 11<sup>th</sup> Victim Compensation Fund (VCF) Assistance
4. External Work-Related, Union-Related, and/or Disability Assistance
5. Social Services Assistance
6. Cancer Care Resources Assistance
7. Care for Non-Covered Health Conditions Assistance

### **Benefits Counseling**

The WTC Health Program will provide a Benefits Counseling handbook and reference materials (fact sheets) related to these 7 categories. In some case, the CCE may be in a better situation to refer a member to external sources (e.g., workers comp, external work-related, union-related and/or disability benefits). Information will be provided by the WTC Health Program related to external networks for many services, but the CCE should also work to build external networks where needed to meet member needs.

The CCE should also be prepared to participate in monthly benefits counseling coordination conference calls and provide monthly metrics related to benefits counseling services provided (type, number, and complaints received related to services provided).

#### **Examples of benefit counseling include:**

- Explaining the benefits and covered services offered under the WTC Health Program, including WTC-related health conditions and medically associated WTC-related health conditions and limitations, and any conditions associated with the receipt or use of benefits.
- Answering general questions related to available benefits.
- Assessing the need for further social services and socioeconomic needs beyond the scope of WTC Health Program coverage (i.e., primary care, housing, food, finances, Worker's Compensation or Disability claims, legal help, education or occupational training, scholarships).
- Being an advocate for patients with profound physical or mental impairment who need assistance.
- Finding providers for members to contact for non-WTC-related medical conditions.
- Assessing member concerns.
- Providing a member's benefit information package with contact information for the member's case manager.
- Provide information on the VCF as directed in the Zadroga Act.

Mental health services are explored during the member's monitoring exam by experienced mental health case managers, using guidance from the screening and diagnostic survey instruments. Physical health program benefits, such as pharmaceutical benefits, and diagnostic or treatment services are considered during the member's physician examination and nurse interview, so that available services are designed to fit each member's individual health care issues.

The CCE's Operations Manual shall provide the details of the Benefit Counseling Plan.

#### ***C.3.7.4 Care Coordination and Integrated Case Management***

The CCE shall provide Case Management services to all members at all clinical interface levels of the program (e.g., Monitoring, Survivor Screening, non-cancer Diagnostics, Cancer Diagnostics, non-cancer Treatment and Cancer Treatment). Case Managers shall address the unique health care needs of individual members and improve client satisfaction with the program. Case Managers shall provide the whole spectrum of case management for all clinical and non-clinical services including, but not limited to, social services, assisting in scheduling visits, coordinating care between providers, and facilitating appeal requests. The CCE's Case Management staffing plan shall include the professional qualifications and skills required for clinical and social case management personnel, clinical coordination, appropriate recognition and handling of urgent or emergent psychiatric or medical situations, managing conflict, and administrative problem solving. The Case Management staffing plan shall be included in the PMP's CCE staffing plan.

Case management is a specialized and highly-skilled component of care management. Case management emphasizes a collaborative process that assesses, advocates, plans, implements, coordinates, monitors, and evaluates health care options and services so that they meet the needs of the individual member. Case management services should be provided to members according to their level of services needed, from low to a higher level of care management.

The case managers should be responsible for maintaining excellent communication with the member's Patient Centered Medical Home (to notify this provider of evaluations and treatment performed through the WTC Health

Program and to notify them about conditions and care that is not covered by the WTC Health Program but will need to be addressed by the Patient Centered Medical Home provider), the CCE/NPN (i.e., between CCE/NPN providers, with the Medical Director, and with other administrative/support staff as needed to facilitate and coordinate the best possible care within the CCE/NPN), the member's specialty providers, social services providers, supportive community resources, other insurers (in the case of survivors enrolled at the survivor CCE and/or the NPN for the purposes of coordinating benefits and in the case of responders, to assist with enrollment in other available health plans for coverage of non-WTC related health conditions if needed and possible) and with the WTC Health Program to ensure the best possible continuity and coordination of care for WTC Health Program members. The case managers should also have a system/process to deal with emergency/high-risk members and cases (e.g., multiple hospital readmissions, psychiatric emergencies, emergency discharge planning, emergent social issues, etc.). The case managers should also have a system/process for smoothly dealing with Hospitalizations, Skilled Nursing Facilities, Extended Care Facilities/Plans (for both physical and mental health conditions covered by the WTC Health Program), Rehabilitation Facilities, Home Health Care, Hospice Care and End of Life Care.

The CCE shall have knowledge and understanding of its member population and ensure continuum of care is being coordinated from pre-acute, acute to post-acute phases. The CCE case management process shall ensure all referrals and referrals of prior referrals are coordinated and service summary reports are maintained. All referred rendering and billing providers shall be registered with the WTC Health Program prior to billing and must be informed of the prior approved services needed (in a non-emergency situation).<sup>10</sup>

The CCE's Operations Manual shall provide the details of the case management program. At the minimum, the case management program should address these key elements:

- Qualification of personnel and training
  - Registered Nurse
  - Licensed Social Worker
  - Clinical
  - Health education
  - Counseling
  - Benefits navigation
- Acuity assessment and ongoing evaluation
- Flow of care including referral tracking
- Care coordination
- Clinical outcomes
- Quality assurance
- Satisfaction with services
- Case management tools
- Communication
- Documentation and records management

Recent work by NQF's (2010) National Priorities Partnership focuses measurement development priorities on the following goals: (1) improve care and achieve quality by facilitating and carefully considering feedback from all patients regarding coordination of their care, (2) improve communication around medication information, (3) work to reduce 30-day readmission rates, and (4) work to reduce preventable Emergency Department visits by 50 percent. The measures highlighted in this work focus on coordination in specific areas of clinical care, such as cardiac rehabilitation, stroke, and cancer, as well as transitions from inpatient to other settings.<sup>11</sup>

#### **Case management model for registered nurses (RN) and social workers (SW)**

In addition to care coordination and integrated case management services for clinical care, the CCE contractor shall develop the workflow similar to clinical service for non-clinical services that require intensive support of the Social

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<sup>10</sup> Further policy guidance on post-acute care case management is forthcoming.

<sup>11</sup> <https://pcmh.ahrq.gov/page/coordinating-care-medical-neighborhood-critical-components-and-available-mechanisms>

Worker case management service, such as social benefits, medical appeal, and assistance with other social benefits related.

Every WTC Health Program member requiring case management services is assigned either an RN or SW case manager. A comprehensive case management approach shall be provided by a team of RNs, SWs and other members of the case management team overseen by the Medical Director and Administrator of the CCE to collaborate when both complex medical and psychosocial factors are identified that may adversely impact the member's health.

1. RN Case Manager addresses the medical, nursing, and/or personal care needs of the WTC Health Program member to enable their return to an optimal level of functioning. Identification of cost-effective resources while providing quality care is necessary to reach the desired outcome and is an essential component of case management services. RNs conduct a comprehensive assessment of the member (and family/caregiver with consent). RNs also support systems that identify actual or potential problems, set health care goals, reassess the member's progress towards those goals, and adjust the member's health care plan as needed in collaboration with the CCE's multidisciplinary health care team.
2. SW Case Manager addresses the individual's bio-psychosocial status, social system, and resources. SWs develop and maintain a therapeutic relationship with the member, which may include linking the WTC Health Program member with systems that provide needed services, resources, and opportunities. SWs demonstrate their expertise by navigating complex health and social service systems, combined with their unique psychosocial perspective, in assisting the member (and family/caregiver with consent) to access resources to maximize the member's well-being.

The CCE contractor shall provide clearly defined RN, SW and other members of the case management team roles, responsibilities and functions related to standards of practice.

#### **Differing levels of intensity of case management approach**

The CCE contractor shall define case management actions within each level of intensity or event that correlate to accepted case management standards of practice. As the member's recovery continues and their health and psychosocial needs stabilize, it is anticipated that less intensive case management services, and thus fewer contacts with the case manager, will be required with eventual discharge from case management services. It is also expected that members who have progressed in the continuum may experience significant life events resulting in the need to return to more intensive case management services. The CCE shall define different levels of intensity of case management that may include, but are not limited to:

- (1) Intensive-Acute Case Management requires daily or weekly patient and family/caregiver contact whenever there is transition of care or significant change in the clinical, psychosocial, functional, or mental health status, such as: a new medical diagnosis, newly identified behavioral health changes, or significant change in lifestyle.
- (2) Progressive-Chronic Case Management requires at least monthly patient and family/caregiver contact to ensure a support system is in place. The member is clinically stable but still needs ongoing intervention for psychosocial or other clinical issues to ensure continuous coordination of care and access to services.
- (3) Supportive-Chronic Case Management requires, at a minimum, quarterly patient and family/caregiver contact to allow for the monitoring of the member's care plan when the member's clinical and psychosocial issues are stable. Quarterly contact also allows the CM to ensure that the member is well established in the system of care.
- (4) Lifetime-Chronic Case Management ensures consistent access to, and collaboration for, care delivery at the WTC Health program's network of medical providers and facility, with local or community resources.

The CCE contractor shall provide the Case Management Process Flow Chart and Case Management approach that demonstrates all levels of care and acuity phases, and include post-acute service in home/community services, as part of the essential elements of case management program described above. The case management program shall be included as part of the CCE's Operations Manual.

#### ***C.3.7.5 Social Benefits Functions***

The CCE shall provide social benefits evaluations and assistance when needed. These services shall include assistance with identifying and completing paperwork to access external social programs for assistance with housing, transportation, food, or medical services outside of those covered by the WTC Health Program. The CCE's Operations Manual shall provide the details of the process to provide social services functions.

#### ***C.3.7.6 Medical Appeals***

The CCE shall inform all members about the medical appeals process for the WTC Health Program that will be specified in regulations at 42 C.F.R. pt. 88, as required in sections 3312(b)(1)(B)(iii) and 3312(b)(2)(B)(iv) of the Zadroga Act. The CCE's Operations Manual shall provide the details of the medical appeals guidance activities.

#### ***C.3.7.7 Medical Reviews***

For a WTC-related health condition or a health condition medically associated with a given WTC-related health condition, a provider shall provide medically necessary treatment that will be specified in regulations at 42 C.F.R. pt. 88, as required in section 3312(b)(3)(B) of the Zadroga Act. The treatment will also be in accordance with established WTC Health Program treatment protocols created by the DCs in collaboration with the CCEs and approved by the WTC Health Program Administrator. If a member is denied treatment and requests a review of that decision by the CCE Director, the member shall be instructed by the CCE to send a letter to the CCE Director describing the treatment denied and the reasons for believing that the treatment is medically necessary for a WTC-related health condition or medically associated WTC-related health condition. The CCE Director will review the request and respond in writing to the member of the final decision and provide the rationale. The CCE will furnish a copy of the letter to the WTC Health Program Administrator and keep records of the review process.

The CCE will also track such decisions and make recommendations to the DC, as appropriate, and to the WTC Health Program Administrator regarding adjustments to program treatment protocols. The CCE's Operations Manual shall provide the details of the medical review process and records system.

#### ***C.3.7.8 Assistance with Workers' Compensation and other Healthcare Benefits***

WTC Health Program members may have access to other sources of health benefits such as workers' compensation, other benefit programs for work-related injuries or illnesses, health insurance, disability insurance, or other insurance plans.

For WTC survivors, a CCE shall require patients to provide documentation of their insurance coverage. The billing system will be set up with codes corresponding to insurance companies and plans with which the CCE has billing arrangements. The CCE shall submit bills for patient care rendered at its facilities to Medicaid; Medicare; commercial, employment-based (e.g., workers' compensation), no-fault and liability insurances; and for self-pay before seeking reimbursement from the WTC Health Program. Furthermore, alternative methods shall be explored to help people pay their medical bills, such as reduced fees, and applying for public health insurance after conducting a comprehensive financial assessment interview with any uninsured or underinsured patients to determine what publicly funded health insurance benefit program (e.g., Medicaid) and/or employment-based medical insurance benefits a patient may potentially be eligible for, or may already have. If a patient is determined to be eligible for participation in a publicly-funded health insurance benefit program, then an enrollment application process shall be started for submission to the appropriate agency. This process shall be monitored from submission to its approval or denial. If a patient is denied participation in a publicly-funded health insurance benefit program like Medicaid, then any fees shall be based on a patient's income and family size.

WTC Health Program members who experienced an injury or emotional trauma resulting from the WTC attack are eligible to apply for Workers' Compensation benefits. Because there can be an extended period of time between the time a claim is filed and when benefits are awarded, the CCE's provision of care and submission of claims shall not be based on expected Workers' Compensation benefits. The CCE shall provide assistance to members with applying for Workers' Compensation benefits and to providers with completing Workers' Compensation

paperwork. Similarly, if other sources of payment are available, the CCE shall assist members in accessing those benefits.

The CCE shall coordinate payment of benefits so that any money received from any other source for medical claims which have already been paid by the WTC Health Program will be reimbursed to the Government. This coordination will be made with the WTC Health Program Administrator. For ongoing healthcare that is paid by other sources, records of those services and the costs that are reimbursed shall be coordinated with the WTC Health Program Administrator.

The CCE's Operations Manual shall provide the details of how all alternative healthcare assistance programs will function.

#### ***C.3.7.9 Member Transfers***

The CCE shall be responsible for assisting with member transfers. The CCEs shall develop a procedure for transferring the care of a member to another entity within the WTC Health Program. The procedure shall also address the transfer of medical records. The CCE's Operations Manual shall provide the details of the member transfer process. All transfers will be made in accordance with WTC Health Program policy and procedures on transfers.

### **C.3.8 Administrative Services**

The following Administrative Services shall be provided by the CCE. The CCE shall develop procedures for providing these Administrative Services. These procedures shall be submitted to the WTC Health Program Administrator for approval as a part of the CCE Operations Manual.

#### ***C.3.8.1 Quality Assurance and Internal Audits***

The CCE's administrative procedures shall include a Quality Assurance component. Responsibilities for Quality Assurance shall include:

- ensuring adherence to monitoring protocols and cancer screening, diagnostic and treatment guidelines
- providing benefits counseling for Workers Compensation and other Insurance Programs
- appropriately billing for only WTC-related health conditions and medically associated health conditions
- ensuring appropriate diagnostic and treatment referrals for members
- verifying prompt communication of test results to members
- reviewing all claim forms and other contract deliverables for completeness and accuracy
- measuring, monitoring, and increasing member satisfaction
- improving overall program success
- quality assessment using medical quality indicators, drug utilization reviews and correction plans (where required)
- early identification and resolution of problems, issues, and risks
- monitoring of adherence to established policies and procedures
- continuous process improvement and implementation of lessons learned
- such other elements as the WTC Health Program Administrator specifies in consultation with the CCE (using various vehicles of transmission such as the Medical Forum teleconference)

The CCE shall be responsible for developing and documenting its approach to Quality Assurance. The CCE shall perform the required services in accordance with their established Quality Assurance Program. The CCE shall develop a project-specific Quality Assurance Plan (QAP) which describes the Quality Assurance Program and the procedures which will be used to monitor and improve all project activities including reporting.

As a part of their QAP, the CCE shall establish a Customer Satisfaction Survey program. Members shall be given the opportunity to complete a Customer Satisfaction survey at least yearly. The annual satisfaction survey shall be conducted within 30 days after the end of the performance year and report results in the corresponding quarterly report. In addition, the members shall be provided a post-visit survey to complete, which shall be analyzed and

reported as part of the quarterly report. The CCE's QAP shall provide details about the proposed Customer Satisfaction survey including frequency and method of surveys, corrective actions to be taken based on survey results, and reporting of survey results to the WTC Health Program Administrator.

In addition, the WTC Health Program Administrator shall receive no more than 3 valid<sup>12</sup> complaints from members about CCE performance during the six month period before the CCE may be placed on a performance improvement plan.

As a part of their Quality Assurance Program, the CCE shall conduct internal audits of their performance at a minimum of every quarter and make these data and findings, including a corrective plan of action, available to the WTC Health Program Administrator and submit them as part of the quarterly report. These audits shall include, but are not limited to:

- **Targeted Health Care Compliance** – The Targeted Health Care Compliance audit shall focus on evaluating the adequacy of the procedures used by the CCE to ensure that only approved WTC-related health conditions and approved health care services (including provider visits, procedures, medication and durable medical equipment) are reimbursed by the program. This includes a review of documentation justifying payment history for medically associated WTC-related health conditions after approval is given by the WTC Health Program Administrator.
- **Medical Management Review** – The Medical Management Review audit shall ensure that medical practice guidelines that have been developed are being followed.
- **Claims History** – The Claims History audit shall focus on irregularities in the claims history of any particular provider or member and shall include rejections and denied claims as well as how many claims are being billed to the members.
- **Medical Records Review** – The Medical Records Review audit shall focus on determining if appropriate procedures have been developed and are being followed for collecting, reviewing, maintaining and securely storing medical records in compliance with HIPAA law and regulations.
- **Personnel Training** – The Personnel Training audit shall focus on ensuring that all personnel performing work under the CCE contract are properly trained and credentialed.
- **Case Management** – Case management service audit shall focus on ensuring the effectiveness of the service, quality of care, outcomes and appropriate use of services.
- **Education and Retention** – Education and retention may include a certain degree of outreach activities and should focus the effectiveness of the activities implemented and meeting of the retention benchmarks.
- **Written and Change Requests** – Written requests including CRs, should focus on responsiveness and timeliness of progress of deliverables and/or implementation of the CRs.
- Any other program implementation, monitoring, and evaluations that will help detect deficiencies and improve the processes that the CCE and/or the COR set.

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<sup>12</sup> Valid complaints include those that are based on member experiences that can be changed and/or that are substantive. Valid complaints include issues such as wait times, cleanliness of a facility, appropriateness of staff, and services provided by the CCE. Complaints that are not considered valid for reporting purposes are those that are based off Program policy or the law. For example, a CCE does not need to report when a member complains that they have to try generic medications first or latency requirements for cancer. A CCE would also not have to report on non-substantive complaints that are not within a CCE's ability to control. For example, if a member complains that the parking lot is too far from the CCE and the CCE has no other options for members parking.

The CCE's Operations Manual shall provide the details of the quality assurance program, and audits findings are to be included in the Quarterly Report.

#### ***C.3.8.2 Records Management***

The CCE shall develop, implement, and administer a comprehensive records management program. This program shall ensure that WTC Health Program records (including medical records) are maintained in a manner such that the information is secure and readily accessible to authorized parties. The records management program shall also address assisting with obtaining medical records, including processing member requests to release protected information. This program shall be approved by the WTC Health Program Administrator and implemented by the CCE within 1 month of the approval. The CCE's Operations Manual shall provide the details of the records management program.

#### ***C.3.8.3 HIPAA Compliance and Business Associate Agreement***

The WTC Health Program, including any other NIOSH, CDC, or HHS components to the extent that they assist in administering the WTC Health Program involving protected health information (PHI), is a Covered Entity for purposes of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The CCE is a business associate of the WTC Health Program as that term is defined in the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules (45 C.F.R. pts. 160, 162, and 164). To the extent that the CCE performs functions or activities on behalf of, or provides certain services to, the WTC Health Program where the CCE creates, receives, maintains, or transmits "protected health information" (PHI), the following "HIPAA provisions" apply: the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104-191; 42 U.S.C. § 1320d); the Health Information Technology for Economic and Clinical Health (HITECH) Act (Pub. L. 111-5; 42 U.S.C. §§ 300jj et seq.); the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules (45 C.F.R. pts. 160, 162, and 164); and HHS HIPAA policies.

The CCE shall require its providers and any and all agents and subcontractors to comply with all applicable provisions of HIPAA, and shall document in writing the policies and procedures that will be used to meet such obligations. The CCE shall provide the WTC Program Administrator with a copy of their Notice of Use and Disclosures of Protected Health Information required by the HIPAA Privacy Rule for review and approval, and ensure in that notice that the Program members are aware the WTC Program Administrator will have access to the member's protected health information for purposes of the treatment provided by and administration of the WTC Health Program established under the Zadroga Act. Furthermore, the CCE's Operations Manual shall provide the details of how the CCE will meet the obligations and activities of a Business Associate of the WTC Health Program.

Attachment #3 contains the WTC Health Program Business Associate Agreement which describes the detailed legal obligations and requirements of the Business Associate and the Covered Entity, including reporting of potential breaches. Any potential offeror shall submit an executed Business Associate Agreement with their proposal. This document shall later be incorporated into the successful awardees' subsequent contract. At all times throughout the duration of the contract and until the CCE fulfills its obligations under the contract and the Business Associate Agreement, the CCE is subject to and shall comply with all applicable HIPAA provisions regarding business associates, as well as any updates to those provisions.

As a Business Associate of the WTC Health Program, the CCE is directly liable under HIPAA for the following violations:

- Impermissible uses and disclosures of PHI;
- Failure to provide breach notification to the WTC Health Program;
- Failure to provide access to a copy of electronic PHI to either the WTC Health Program, the individual, or the individual's designee, as specified in the Business Associate Agreement;
- Failure to disclose PHI where required by the Secretary of HHS to investigate or determine the Business Associate's compliance with HIPAA;
- Failure to provide an accounting of disclosures; and
- Failure to comply with the requirements of the Security Rule.

#### ***C.3.8.4 Transfer of Data and Information***

At the end of the contract or at a time determined by the WTC Health Program Administrator, the CCE shall transfer to the WTC Health Program Administrator or a subsequent contractor all data and information necessary to transition operations, including: medical records, data and reference tables; documentation relating to software and interfaces; functional business process flows; and operational information, including correspondence, documentation of ongoing or outstanding issues, operations support documentation, and operational information regarding subcontractors. For purposes of this provision, "documentation" means all operations, technical and user manuals used in conjunction with the software, services and deliverables, in whole or in part, that the WTC Health Program Administrator determines are necessary to view and extract application data in a proper format. The CCE shall provide the documentation in the formats in which such documentation exists at the expiration or completion of the contract.

The CCE shall provide to the WTC Health Program Administrator all data, information and services necessary and sufficient to enable the WTC Health Program Administrator to map all data from the CCE's system(s) to the replacement system(s) of the WTC Health Program Administrator or a successor contractor, including a comprehensive data dictionary that gives the names and definitions of all data fields in the database.

The CCE shall provide to the WTC Health Program Administrator all necessary data, information and services in the format defined by the WTC Health Program Administrator, and must be HIPAA compliant. All of the data, information and services mentioned in this section shall be provided and performed in a manner by the CCE using its best efforts to ensure the efficient administration of the WTC Health Program. The data and information must be supplied in media and format specified by the WTC Health Program Administrator and according to the schedule approved by the WTC Health Program Administrator. All relevant data and information must be received and verified by the WTC Health Program Administrator. Failure to perform this requirement will be considered as contract non-compliance.

The CCE's Operations Manual shall provide the details of the transfer of data and information and turnover of services procedure.

#### ***C.3.8.5 Other Administrative Responsibilities***

- Attending administrative, steering, benefits, and clinical and other WTC Health Program meetings
- Report writing and IRB submissions
- Data entry for claims submission and to meet reporting requirements
- Data entry of healthcare information into the DC's data system
- Providing intellectual input on the refinement of medical guidance and protocols as needed by the program or in support of member treatment needs
- Providing administrative personnel to support the CCE's contract
- Providing translational and interpretive services
- Providing facilities for providing the services required under the CCE contract.

The CCE's Operations Manual shall provide the details of how these other administrative services will be provided.

### **C.9 Clinical Center of Excellence Services Summary Table/Quality Assurance Surveillance Plan (QASP)**

The offeror shall establish and continuously operate an internal quality management/quality improvement program covering every aspect of its operation, both clinically and administratively. The offeror shall provide a quarterly written report and briefing in person or via video teleconference to the COR and NIOSH staff on its ongoing internal quality improvement program. The offeror shall submit a draft Quality Assurance Surveillance Plan as part of the QAP based on the following suggested metrics as part of its proposal:

<b>Performance Objective</b>	<b>PWS Para.</b>	<b>Performance Threshold</b>	<b>Surveillance Method</b>	<b>Defect and Remedy</b>
1. Communication with the WTC Health Program	C.3.1 CCE Contract Management	The contractor shall respond within the specified or agreed to deadlines 100% of the time.	100% inspection based on information maintained by WTC Health Program	Two (2) late responses during a six (6) month period will lower the contractor performance rating. Three (3) late submissions per 6 months will require a corrective action plan.
2. Timeliness of Deliverables	C.3.1 CCE Contract Management C.12 Deliverables	All deliverables including routine and adhoc reports are delivered within required timeframes.	100% Inspection based on information maintained by WTC Health Program	Two (2) late submissions per six (6) months will lower the contractor performance rating; three (3) late submissions per six (6) months will require a corrective action plan.
3. Fraud, Waste, and Abuse Report	C.3.1 CCE Contract Management	The quarterly Fraud, Waste, and Abuse Report shall be submitted no later than 30 days from the end of the quarter 100% of the time	100% inspection based on information maintained by WTC Health Program	One (1) late submission per six (6) months will require an immediate corrective action plan.
4. Conduct Quality Assurance Internal Audits	C.3.1 CCE Contract Management	Quality Assurance Internal Audits shall be conducted quarterly on contract activities and summary audit report delivered within 45 days from the end of each quarter.	Random monitoring/ periodic inspection as agreed upon between the contractor and WTC Health Program.	One (1) late submission per six (6) months will require an immediate corrective action plan.
5. HIPAA Compliance and Business Associate Agreement	C.3.8 Administrative Services	All suspected breaches by either the CCE or their subcontractors will be reported to the CO, COR and WTC Health Program HIPAA Privacy Officer within 10 business days of discovery 100% of the time.	100% inspection	One (1) late submission during the period of performance will require a corrective action plan.
6. Member's Valid Complaints about Treatments, Services, and Medical Decisions	C.3.7 Member Services	WTC Health Program should receive no more than two (2) valid* complaints from members about contractor performance during a quarter.	100% inspection based on information maintained by WTC Health Program  *“Valid” means that WTC Health Program has sought input from the contractor and confirmed that the complaint is real and has merit.	Three (3) valid complaints per six (6) months will lower the contractor performance rating. Six (6) valid complaints per six (6) months will require a corrective action plan.
7. Case Management Services	C.3.7 Member Services	Monitor and evaluate quality and performance of case management including: completeness of documentation, workload and productivity records, baseline and continuous case management, utilization of services, flow of care, clinical outcomes, cost, and customer satisfaction.	Review completeness of documentation  Review member inquiry turnaround time  Review case managers' qualification  Random monitoring/ Periodic inspection  Customer complaints	If documentation is found to be incomplete and/or member inquiry are not provided in a timely manner and/or more than 2 complaints in one (1) month, will result in a lower performance rating. If more defects continue to persist in the following month, a corrective action plan is required.

8. Enrollment and Registration of Credential Providers	C.3.4 Healthcare Provider Network	All service rendering providers are registered in the WTC Health Program's Provider Network prior to claims submission. Ensure that all internal and external providers, including cancer providers, are credentialed, trained and registered in the claims system prior to submission of claims. For each month, 100% records will be evaluated and no more than 1 provider will not be registered.	Random monitoring/ periodic inspection as agreed upon between contractor and WTC Health Program  Credentialing and training records  Denied claims records due to providers not enrolled.	A finding in one month of not meeting the QA measure will result in randomly selecting an additional 25 claims for evaluation, if more were submitted. If the QA measure is not met in 1 month, the CCE will immediately obtain required information and provide it to WTC Health Program. Two consecutive months of not meeting the QA measure will result in a corrective action plan and/or lower performance rating. A corrective action plan is required and the contractor is subjected to a lower performance rating.
9. Provide Monitoring Evaluation Results to Members	C.3.2 Monitoring and Initial Health Evaluations	Each month provide 95% of monitoring evaluation results in the form of electronic or hard copy letters within 10 business days of completing the monitoring exam and 100% of letters within 15 business days.	Random monitoring/ periodic inspection as agreed upon between contractor and WTC Health Program  Review of quarterly report	Failure to meet the two performance thresholds each month will require a corrective action plan and result in a lower performance rating.  The monitoring evaluation results may be presented to the member in person, via a secured electronic communication (i.e., patients' portal), or by mail.
10. Provide Summary Reports to Physical Exam Physicians	C.3.2 Monitoring and Initial Health Evaluations	The contractor shall ensure that the physician who conducts the physical examination always has a copy of the summary report in time to review it before conducting the responder's physical examination.	Random monitoring/ periodic inspection as agreed upon between contractor and WTC Health Program	If at least two (2) summary reports are not provided in a timely manner per month, a corrective action plan will be required and it will result in a lower performance rating.
11. Length of Time Diagnostic Plans are made available to Members	C.3.2. Monitoring and Initial Health Evaluations	The contractor shall make diagnostic plans available to members for 12 months after diagnostic workups. Diagnostic plans should be provided to members upon written request within five (5) business days of receiving properly completed and signed release form (copies are acceptable) 100% of the time; follow-up with previous providers within 15 days 100% of the time.	Random monitoring/ periodic inspection as agreed upon between contractor and WTC Health Program	If any of the three (3) performance thresholds are not met for two (2) consecutive months, it will result in a lower performance rating. If two (2) of the performance thresholds are not met in a month, a corrective action plan is required.
12. Update contact information for all members annually	C.3.7 Member Services	A protocol for reaching out to members that is agreed to by the contractor and WTC Health Program will be followed to contact all members annually to update contact information.	Random monitoring/ periodic inspection as agreed upon between the contractor and WTC Health Program	If more than 1% of members are not accounted for by the protocol in the annual update, a corrective action plan is required.

13. Acquiring previous medical records	C.3.2 Monitoring and Initial Health Evaluations	Each month, request signature of members for needed medical records release forms 100% of the time; request records from previous providers within three (3) days of contractor receiving properly completed and signed release form (copies are acceptable) 100% of the time; follow-up with previous providers within 15 days 100% of the time.	Random monitoring/ periodic inspection as agreed upon between the contractor and WTC Health Program	If any of the three (3) performance thresholds are not met for two (2) consecutive months, it will result in a lower performance rating. If two (2) of the performance thresholds are not met in a month, a corrective action plan is required.
14. Review, approve, and submit the appropriate claims	C.3.5 Claims Submission and Payment	For internal claims for any type of service, the Current Timely Filing Policy dated Nov 23, 2015, includes a requirement that 95% of internal claims be submitted within 1 month of date of service, 80% of external claims without COB be submitted within 12 months of the date of service, and 75% of external claims with COB be submitted within 15 months of date of service.	Random monitoring/ periodic inspection as agreed upon between the contractor and WTC Health Program	Any claims not reviewed each month will result in re-performance of the review. If at least three (3) claims do not meet the performance threshold for two (2) consecutive months, it will result in a lower performance rating. If at least six (6) claims do not meet the performance threshold for two (2) consecutive months, a corrective action plan is required.

## C.10 Background and Experience

The CCE shall have relevant experience in treating environmental and occupational exposure health issues with a minimum of five years in providing healthcare services of a type similar or greater in scope, size, and complexity to those required under the WTC Health Program. Relevant experience should include:

The physicians who will be conducting the medical monitoring assessments and physical examinations shall be experienced in practicing occupational medicine, internal medicine or family medicine (e.g., conducting occupational health screening and medical surveillance); preferably board-certified specialists. The CCE shall develop training to properly instruct the participating CCE providers about the potential exposures and health outcomes that have been associated with the WTC attack and the conditions and services covered by the WTC Health Program.

- Initial and Medical Monitoring Evaluations
- Diagnostic and Treatment Services
- Member Services
- Administrative Services
- Case Management

## C.11 Personnel

The CCE shall have personnel assigned to this project that have the experience, educational background, and record of past accomplishment appropriate to the scope of the effort. The CCE shall employ health care provider staff with expertise that includes, at a minimum, occupational medicine, environmental medicine, trauma-related psychiatry and psychology, and social services and benefits counseling.

The CCE shall list all personnel designated as Key Personnel for this contract along with their years of relevant experience and the functions they will perform on this contract.

At a minimum, Key Personnel shall include a Clinic Director and a Clinic Administrator. The Clinic Director shall have overall responsibility for the CCE contract and shall serve as the CCE's primary point of contact with the WTC Health Program Administrator on all issues, including medical matters. The CCE Clinic Director shall be highly knowledgeable of all aspects of the WTC Health Program. The CCE Administrator shall serve as the CCE's secondary point of contact with the WTC Health Program Administrator on policy and non-medical issues. The CCE Administrator shall be highly knowledgeable of all operational aspects of the WTC Health Program.

In addition to Key Personnel, the CCE shall provide the personnel necessary to accomplish all activities required to implement the CCE contract requirements. The CCE shall establish a clear chain of command, communication and organization at all management levels and may assign a Program Manager to assist with day-to-day operations, and Case Management Team Leads who are certified case manager (i.e., RN and SW) to oversee a case management program. The staffing plan shall reflect the practical level of efforts required according to the CCE's operational size and capability. The CCE shall provide a Staffing Plan with the proposal that clearly demonstrates appropriate levels of function and organization.

The CCE shall have appropriate oversight of all personnel to ensure they are complying with Program policy, are filling a vital role in the operation of the CCE, and are providing quality work. No personnel without clinical training and qualifications, including providing prescribed medication information, shall be authorized to make clinical decisions within any aspect of the CCE's operations,

## **C.12 Deliverables**

All deliverables required under this contract shall be packaged, marked and shipped in accordance with the guidance found in this section. The CCE shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

Reports submitted under the contract shall reference and cite the contract number and identify HHS CDC NIOSH as the sponsoring agency. All contract deliverables must be reviewed and approved by the WTC Health Program Contracting Officer (CO) and the Contracting Officer's Technical Representative (COTR). Satisfactory reporting performance under the contract shall be deemed to occur upon delivery and acceptance by the CO, or the duly authorized representative, of the following items:

The data and analyses to be reported to the WTC Health Program Administrator shall include all information required to effectively administer and manage the CCE contract. Minimum required data are listed below. The CCE shall provide a listing and short description of standard reports that will provide these data and analyses of these data, as well as any other data and analyses that the CCE considers to be valuable to the WTC Health Program Administrator. All reports shall be submitted monthly unless otherwise specified. The CCE shall certify the completeness and accuracy of the reports submitted pursuant to this section. The certification shall be in the manner and format currently established by the WTC Health Program Administrator and shall attest, based on the CCE's best knowledge and belief, to the accuracy, completeness and truthfulness of the reports being submitted. The CCE shall ensure that the WTC Health Program Administrator does not receive any personal data on the members (names or other identifiers) in these reports.

The CCE shall base their proposed reporting formats and content on their experience with other similar programs. The CCE shall analyze the data collected during each reporting period and ensure that all reports provide summaries which highlight significant trends. All reports shall include a narrative companion text document that summarizes the report data and explains any unusual occurrences or trends.

### C.12.1 Deliverables Required by the PWS & Information Technology Security and Privacy

PWS Reference (Attachment #1)	Deliverable Title	Date Due
C.3.1.1	Project Management Plan	Draft with proposal; finalized version within 30 days of contract award; updates monthly
C.3.1.2	Operations Manual	Draft with proposal; finalized version within 60 days of contract award; updates monthly
C.3.1.3	Communications Plan	Draft within 60 days of contract award; finalized version 2 weeks upon receipt of comments; updates monthly
C.3.1.4	Data Security and Continuity of Operations Plan	Draft within 60 days of contract award; finalized version 2 weeks upon receipt of comments; updates monthly
C.3.1.5	Risk Management Plan	Draft within 60 days of contract award; finalized version 2 weeks upon receipt of comments; updates monthly
C.3.1.6	Fraud, Waste and Abuse Compliance Plan	Draft within 60 days of contract award; finalized version 2 weeks upon receipt of comments; updates monthly
C.3.1.7	Quality Assurance and Internal Audit Plan	Draft with proposal; finalized version within 60 days of contract award, updates monthly
C.3.1.9	Subcontracting Plan	Draft with proposal; finalized version within 30 days of contract award, updates 30 days before revision
C.3.1.12	Program Improvement Plan	Draft within 60 days of contract award; finalized version 2 weeks upon receipt of comments; updates monthly
C.3.5 C.3.7.4	Coordination of Benefit Plan	Draft with proposal; finalized version within 60 days of contract award; updates monthly
C.12.2	Monthly Report	The 10 <sup>th</sup> day of the month for the previous month's information
C.12.3	Quarterly Report	The 45 <sup>th</sup> business day reporting on the previous quarter's activities. The quarterly report shall include other corresponding reports that are due Semi-Annually
C.12.4	Additional Administrative Reports	No more than 2 quarterly
IT Reference (Attachment #2)	Deliverable Title	Date Due
7.3	PII Security Plan	Draft with proposal; finalized version within 30 days of contract award; updates monthly
7.3.3	System Security Plan	Draft within 45 days of contract award; finalized version 2 weeks upon receipt of comments; updates monthly
17.3-17.5	FIPS 199; SA&A; SSP; SAR; POA&M; Contingency Plan	Due within 45 days of contract award

### C.12.2 Monthly Reports

The CCE shall submit monthly status reports on Member Services and Administrative Services activities. The status reports shall provide sufficient detail for the WTC Health Program Administrator to track all significant program activities, operations and progress. The reports shall summarize the activities and accomplishments of the past month (including the associated cost for these services invoiced to the government) and identification of any potential risks to continued program success (along with the plans to mitigate the risk).

#### C.12.2.1 Member Services Monthly Report

Member Services Monthly Report Due on the 10 <sup>th</sup> business day of the month for previous month's activities	
Member Service Function	Information to Be Reported
Monitoring and Initial Health Evaluations	Highlights and summary of analysis of monitoring and initial evaluation statistic from the previous two months comparing with billing period (total of three months) and the associated cost for these services invoiced to the government.
Cancer Screening, Diagnostic and Treatment Services	Highlights and summary of analysis of cancer screening, diagnostic and treatment services statistic from the previous two months to

	comparing with billing period (total of three months) and the associated cost for these services invoiced to the government.
Information and Education	Highlights and summary of analysis of effectiveness of information and education activities performed during the period and the associated cost for these services invoiced to the government.
Program Benefits Counseling	Highlights and summary of analysis of effectiveness of program benefits counseling activities performed during the period and the associated cost for these services invoiced to the government.
Care Coordination and Integrated Case Management	Highlights and summary of analysis of effectiveness of high level of clinical and/or non-clinical care being coordinated, including primary and secondary referrals, and transition from acute to sub-acute to local home and community-based services during the period and the associated cost for these services invoiced to the government.
Social Benefits Functions	Highlights and summary of analysis of effectiveness of social benefits activities performed during the period and the associated cost for these services invoiced to the government.
Medical Appeals and Reviews	Highlights and summary of analysis of effectiveness of Medical Appeals and Reviews performed during the period and the associated cost for these services invoiced to the government.
Assistance with Workers' Compensation and other Healthcare Benefits	Highlights and summary of analysis of effectiveness of activities related to assistance with workers' compensation and other healthcare benefits performed during the period and the associated cost for these services invoiced to the government.
Member Transfers	Highlights and summary of analysis of member transfer services performed during the period (including the status of all outstanding requests for medical records) and the associated cost for these services invoiced to the government.
Member complaints	Highlights and summary of analysis of members' resolved and unresolved valid complaints related to member services, treatment, and medical decisions during the period and the associated cost for these services invoiced to the government.
Other Member Services	Highlights and summary of analysis of other member services performed during the period and the associated cost for these services invoiced to the government.

### ***C.12.2.2 Administrative Services Monthly Report***

<b>Administrative Services Monthly Report</b> <b>Due on the 10<sup>th</sup> business day of the month for previous month's activities</b>	
<b>Administrative Service Function</b>	<b>Information to Be Reported</b>
Healthcare Provider Network	Highlights and summary of analysis of participation in external providers' network and managing internal providers' network performed during the period and the associated cost for these services invoiced to the government.
Pharmacy Benefit Management (PBM)	Highlights and summary of analysis of PBM services provided and coordination with the WTC Health Program Pharmacy Benefit Manager performed during the period and the associated cost for these services invoiced to the government.
Records Management	Highlights and summary of analysis of records management activities performed during the period and the associated cost for these services invoiced to the government.
HIPAA Compliance	Highlights and summary of analysis of HIPAA compliance activities including potential and/or confirmed violations as defined by the WTC Health Program that occurred during the period and the associated cost for these services invoiced to the government.
Attending administrative, steering, benefits, and clinical WTC Health Program meetings	Highlights and summary of analysis of goals and outcomes of meetings/events attended during the period and the associated cost for these services invoiced to the government.
Change Request (CR), Report Writing and Responding to Government Inquiries	Highlights and summary of analysis of activities related to CR, report writing and responding to government inquiries during the period and the associated cost for these services invoiced to the government.

Claims Review, Approval, And Submission Of Clean Claims Appropriate Claims	Highlights and summary of analysis of activities related to claims processing activities performed during the period and the associated cost for these services invoiced to the government.
Healthcare Protocol Development - provide intellectual input on the development and refinement of medical guidance and protocols as needed	Highlights and summary of analysis of activities related to healthcare protocol development during the period and the associated cost for these services invoiced to the government.
Mass Communication, Press and Media Release and Interpretation and Translation Service	Highlights and summary of analysis of activities related to mass communication, press and media release and interpretation and translation services planned and completed during the period and the associated cost for these services invoiced to the government.
Balancing of budget and invoicing	Monthly invoice shall include all CLINs itemized balancing sheets and projection of when the 75% of awarded fund is expected to occur. The CCE is not authorized to operate beyond the approved budget ceiling. A justification shall be provided with unusually low or high invoicing amount. Invoice shall reflect accurate and valid activities required under this contract for the billing period
Key Personnel and Staffing Changes	Summary of key personnel and/or staffing changes and analysis of impacts and the associated cost invoiced to the government during the period. A resume of new key personnel shall be provided.
Subcontracting	Summary of subcontracting activities and changes with operational impacts and associated cost invoiced to the government during the period.
Other Administrative Services	Highlights and summary of analysis of other administrative services, including the nature of these services and the associated cost invoiced to the government during the period.
Operations Manual, Program Management and other Plans	Highlights and summary of analysis of any changes required due to new Program policy or operational difficulties encountered and proposed changes are required. All change requests and updates to any approved plans shall be submitted for approval prior to an implementation.
Fraud, Waste, and Abuse (FWA) Report	<p>A) The CCE contractor shall submit monthly the number of complaints of FWA made to the CCE contractor related to covered services that warrant preliminary investigation by the CCE contractor.</p> <p>B) The CCE contractor shall also submit to the WTC Health Program the following on an ongoing basis for each confirmed case of fraud, waste, or abuse it identifies through complaints, organizational monitoring, contractors, subcontractors, providers, and members, etc. related to covered services:</p> <ol style="list-style-type: none"> <li>1) The name of the individual or entity that committed the fraud, waste, or abuse;</li> <li>2) The source that identified the fraud, waste, or abuse;</li> <li>3) The type of provider, entity or organization that committed the fraud, waste, or abuse;</li> <li>4) A description of the fraud, waste, or abuse;</li> <li>5) The approximate dollar amount of the fraud, waste, or abuse;</li> <li>6) The legal and administrative disposition of the case including actions taken by law enforcement officials to whom the case has been referred; and</li> <li>7) Other data/information as prescribed by the WTC Health Program.</li> </ol> <p>Such report shall be submitted when cases of fraud, waste, and abuse are confirmed, and shall be reviewed and signed by an executive officer of the CCE contractor.</p>

**Format** - Except as otherwise specified herein, the CCE shall prepare and submit to the WTC Health Program Administrator the reports required under this section in an agreed-upon media format on the 10<sup>th</sup> business day of the month for the previous month's activities.

The WTC Health Program Contracting Officer may extend due dates or modify report requirements or formats upon a written request by the CCE to the WTC Health Program Contracting Officer, where the CCE has demonstrated a good and compelling reason for the extension or modification. The determination to grant a modification or extension of time shall be made by the WTC Health Program Contracting Officer.

### C.12.3 Quarterly, Semi-Annually, and Annual Reports

<b>Quarterly Internal Audit Report</b> <b>Due on the 45<sup>th</sup> business day of the quarter, reporting on the previous quarter's activities</b>		
<b>Administrative Service Function</b>	<b>Information to Be Reported</b>	<b>Frequency</b>
Targeted Health Care Compliance audit shall focus on evaluating the adequacy of the procedures used by the CCE to ensure that only approved WTC-related health conditions and approved health care services (including provider visits, procedures, medication and durable medical equipment) are reimbursed by the program. This includes a review of documentation justifying payment history for medically associated health conditions after approval is given by the WTC Health Program Administrator.	The CCE shall report on Quality Assurance activities performed (including analysis of data and quality improvement) to ensure the CCE follows appropriate authorization channels for all treatment services, including medications, and coordinates referrals for treatment to ensure that the treatment being provided is for a qualifying, certified condition, is consistent with the program treatment protocols and that the treatment is medically necessary.	Element to be reported every quarter
Drug Utilization Review (DURs) and Analysis of PBM Reports: <ul style="list-style-type: none"> <li>• Percentage of generic medications vs. brand name medications filled.</li> <li>• Analysis of controlled substance use.</li> <li>• Individual prescriber analysis.</li> <li>• Preferred vs. non-preferred medications filled.</li> </ul>	The CCE shall conduct DURs according to policy guidance issued as part of the technical guidance and/or the PPM and coordinate with the WTC Health Program to obtain reports for analysis of its members' pharmacy benefits usages.  There must be medical necessity documented for all prescriptions reviewed retrospectively and they must meet all requirements stated in the formulary and PPM and other related technical guidance. If a medication is found to be inappropriately filled through the WTC Health Program by the CCE, the CCE shall ensure that the Program is notified in accordance with procedures stated in the PPM and technical guidance prepared to ensure future fills of that medication will no longer be billed to the WTC Health Program.	Element to be reported every quarter
Pharmacy claims history audit shall focus on irregularities in the claims history of any particular provider or member.	The CCE shall coordinate with the WTC Health Program PBM to weekly obtain and review 100% of all covered cancer certified patients' medications claims for adherence to NCCN guidelines. The CCE shall also conduct DUR for members certified for only non-cancer conditions by reviewing a 5% sample of the total number of paid claims to assess whether the certification of categories of health conditions on file matches the therapeutic class of medication dispensed.	Element to be reported every quarter
CCE shall ensure that claims from internal and external providers are processed within WTC Health Program policy timeframes. All claims for internal services must be submitted as clean claims within 30 days of the dates of service.	Claims from external providers must be reviewed and approved or denied within one week of external provider claims being posted for review. The CCE shall submit 95% of all internal services as clean claims within 30 days of the dates of service. The CCE shall describe the specific methodology used for review which will be consistent with the treatment protocols pre-authorized by the CCE and standards of care for the certified health conditions. Each month, a random sample of 25 claims or 100%, whichever is less, will be evaluated and no more than 1 claim will be submitted later than 30 days. Any deviation shall be reported along with the CCE's improvement plan.	Element to be reported every quarter

Member Retention	The CCE contractor will report the number of members who have updated contact information within the 12-month period ending at the previous quarter. As an example, for the 12-month period ending on March 31, 2017, the June 30, 2017, report will give the number of members with updated contact information on or after April 1, 2017. All members will be accounted for in at least one of the three categories above, that their contact information has been verified/updated, that there was no response from the member, or that the required effort to contact the member was not made. There will be no more than 0.5% of members for whom the required annual contacting effort was not made.	Element is to be reported at least quarterly.
Personnel Training: The Personnel Training audit shall focus on ensuring that all performing work under the CCE contract are properly trained and credentialed.	The CCE contractor shall be responsible for ensuring that the health care providers who provide diagnostic and treatment services meet all requirements of the CCE contract, credentialed according to WTC Health Program standards, currently the National Committee for Quality Assurance (NCQA) and to ensure that all providers in the CCE's provider network (whether internal or external) are properly licensed and insured under applicable state laws and/or regulations. The CCE contractor shall report to the WTC Health Program the number of providers that were reviewed and found to be properly licensed and insured on a quarterly basis.	Element is to be reported at least quarterly.
Quality Assurance Projects: the CCE shall report on activities in various program areas where Quality Assurance, Quality Improvement have been performed.	The CCE shall select program areas to monitor and document findings and improvement plans. Once satisfactory results are achieved in a program area, a new area of focus shall be monitored.	Element is to be reported at least quarterly. A new QA project should be selected every year.
Program Management and Improvement	The CCE shall assess overall program management effectiveness and provide any improvement plan or recommendation to the WTC Health Program. Any performance rating below satisfactory in the Contractor Performance Assessment Reporting System (CPARS) shall be addressed and included in a corrective action plan.	Element is to be reported at least Semi-Annually.
Quality Assurance Surveillance Plan (QASP) /Services Summary Matrix and Audit Findings	The CCE shall conduct analysis and provide a summarized report of each QASP item with relevant actions according to its own findings and/or government's audit in accordance with CPARS.	Element is to be reported at least Semi-Annually
Medical Management Review	The CCE shall assess to ensure that medical practice guidelines that have been developed are being followed. All findings that are not consistent with program policies shall be reported along with the CCE's improvement plan.	Element is to be reported at least Semi-Annually.
The Medical Records Review audit shall focus on determining if appropriate procedures have been developed and are being followed for collecting, reviewing, maintaining and securely storing medical records in compliance with HIPAA law and regulations.	Collecting, reviewing, maintaining and securely storing medical records in compliance with HIPAA law and regulations. Performing quality assurance checks, reviewing medical records for completeness and to ensure protocols are followed for: Monitoring and Initial Health	Element is to be reported at least Semi-Annually.

	<p>Evaluations, Treatment Services, Member Services and other services in alignment with WTC Health Program policies.</p> <p>Obtaining relevant medical records for members previously served by another CCE or the NPN. Ensure the provisions of the policy of member transfers between CCEs and the NPN are followed, which includes obtaining signatures of members for needed medical release forms and sending the complete well-documented medical records to the designated party within 2 weeks of receiving the signed release, 100% of the time. The sending clinical location must follow-up to verify the delivery of records is made within 1 week to the receiving clinical location 100% of the time.</p>	
Point of Service and Annual comprehensive customer satisfaction survey	<p>In addition to offering a customer satisfaction survey at the initial and annual monitoring evaluations, diagnostic and treatment visits, and case management interventions, the CCE shall conduct an annual comprehensive customer satisfaction survey and provide an analysis report with a plan of action corresponding to the results of the survey. A total rating of all surveyed categories scored below 95% and or any categories rated below 90% shall be further analyzed and a corrective action plan provided.</p>	<p>Point of Service Satisfaction Survey shall be reported quarterly by month or quarter of analysis. Annual Satisfaction Survey is to be reported annually.</p>

#### **C.12.4 Additional Administrative Reports**

Upon request by the WTC Health Program Contracting Officer, the CCE shall prepare and submit other operational data reports. Such requests will be limited to situations in which the desired data is considered essential and cannot be obtained through existing CCE reports. Whenever possible, the CCE will be provided with a ninety (90) day notice and the opportunity to discuss and comment on the proposed requirements before work is begun. However, the WTC Health Program Administrator reserves the right to give five (5) days' notice in circumstances where time is of the essence. The CCE contractor shall prepare and submit to the Contracting Officer and Program Administrator, through the COR, the other operational data reports in e-mail format.

The CCE shall prepare and submit to the WTC Health Program Contracting Officer and Program Administrator the reports required under this section, in an agreed-upon media format, within twenty (20) business days of the request or as short a period as five (5) business days where time is of the essence and it is feasible to deliver the report within that shorter period.

The WTC Health Program Contracting Officer may extend due dates, or modify report requirements or formats upon a written request by the CCE to the WTC Health Program Contracting Officer, where the CCE has demonstrated a good and compelling reason for the extension or modification. The determination to grant a modification or extension of time shall be made by the WTC Health Program Contracting Officer.

#### **C.13 Period of Performance**

The anticipated Period of Performance for this requirement is:

Base Period: January 1, 2017 – December 31, 2017  
Option Period 1: January 1, 2018 – December 31, 2018  
Option Period 2: January 1, 2019 – December 31, 2019  
Option Period 3: January 1, 2020 – December 31, 2020  
Option Period 4: January 1, 2021 – December 31, 2021

## C.14 FISMA Compliance

### The below information complies with HHS Security compliance requirements for the EGovernment Act of 2002 (FISMA)

The HPS contractor shall have the ability to host and maintain a system for data collection, management, use, and reporting to support activities funded by the federal government. **IMPORTANT NOTE TO OFFERORS:** The following information shall be addressed in a separate section of the Technical Proposal entitled, "Information Security." *Information Security* is applicable to this requirement because all information systems developed, operated, or used by or on behalf of the Federal Government must comply with Federal Information Security laws, regulations, policies and standards. The following information is provided to assist in the preparation of proposals in order to ensure that the existing data system, which would be licensed for use by CDC grantees and CDC employees, meets the security standards described below.

The EGovernment Act of 2002 (Federal Information Management Act) and the below federal policies dictate the framework for ensuring information security for data systems operated by or on behalf of the Federal government. These are summarized below.

OMB Circular A-130 ([http://www.whitehouse.gov/omb/Circulars\\_a130\\_a130trans4/](http://www.whitehouse.gov/omb/Circulars_a130_a130trans4/)) establishes policy for the management of Federal information resources, pursuant to a number of laws and regulations, including the Paperwork Reduction Act of 1980 (amended in 1995), the Computer Security Act of 1987, and other laws. Circular A-130 requires all federal information systems to have security plans, emergency response capabilities, designated individuals who are responsible for security, security awareness training, and regular review of the system. Appendix III of Circular A-130, entitled "Security of Federal Automated Information Resources," establishes a minimum set of controls to be included in Federal automated information security programs; assigns Federal agency responsibilities for the security of automated information; and links agency automated information security programs (such as the DHHS AISSP) with OMB Circular No. A-123.

The Federal Information Security Management Act of 2002 (P.L. 107-347) (FISMA) (<http://csrc.nist.gov/policies/FISMA-final.pdf>) requires each agency to develop, document, and implement an agency-wide information security program to safeguard information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, offeror (including sub-offeror), or other source. The National Institute of Standards and Technology (NIST) has issued a number of publications that provide guidance in the establishment of minimum security controls for management, operational, and technical safeguards needed to protect the confidentiality, integrity, and availability of a Federal information system and its information.

Pursuant to Federal and HHS Information Security Program Policies the following standards and guidelines apply:

- **FIPS Publication 200**, Minimum Security Requirements for Federal Information and Information Systems (<http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf>),
- **FIPS Publication 199**, Standards for Security Categorization of Federal Information and Information Systems (<http://csrc.nist.gov/publications/fips/fips199/FIPS-PUB-199-final.pdf>)
- **NIST Special Publication 800-18**, Guide to Developing Security Plans for Federal Information Systems (<http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf>)
- **NIST Special Publication 800-60**, Guide for Mapping Types of Information and Information Systems to Security Categories Vol. 1 ([http://csrc.nist.gov/publications/nistpubs/800-60-rev1/SP800-60\\_Vol1-Rev1.pdf](http://csrc.nist.gov/publications/nistpubs/800-60-rev1/SP800-60_Vol1-Rev1.pdf)) and Vol. 2 ([http://csrc.nist.gov/publications/nistpubs/800-60-rev1/SP800-60\\_Vol2-Rev1.pdf](http://csrc.nist.gov/publications/nistpubs/800-60-rev1/SP800-60_Vol2-Rev1.pdf)).
- **NIST Special Publication 800-53**, Recommended Security Controls for Federal Information Systems and Organizations (<http://csrc.nist.gov/publications/nistpubs/800-53-Rev3/sp800-53-rev3-final-errata.pdf>).
- **NIST Special Publication 800-63**, Electronic Authentication Guideline ([http://csrc.nist.gov/publications/nistpubs/800-63/SP800-63V1\\_0\\_2.pdf](http://csrc.nist.gov/publications/nistpubs/800-63/SP800-63V1_0_2.pdf))

The Offeror shall demonstrate its understanding of security requirements by attaching a ***Draft Data System Security Plan*** or information system security plan (SSP). The SSP should be a brief and general narrative description of the system and its integration with the CDC Network Infrastructure.

The initial draft and all subsequent versions of the SSP must be prepared and submitted by the Offeror with the Offeror's proposal in Microsoft Word-compatible format. The successful Offeror shall be responsible for ensuring that the security plan is acceptable to the CDC technical monitor and the WTCHP Information System Security Officer (ISSO) as well as any subsequent federal reviewers (e.g., Institute, Center and/or HHS officials, OMB officials, etc.). Comments shall be conveyed to the Offeror by the technical monitor and/or the contracting officer.

Once an award is made, the technical monitor and the contracting officer will review the draft SSP and any subsequent versions and submit recommendations/comments to the Offeror within 14 working days after receipt. The Offeror shall incorporate the technical monitor's recommendations and submit paper and electronic copies of the security plan to the contracting officer and to the technical monitor within five working days after receipt of the technical monitor's comments. The resultant contract will require the draft SSP to be finalized in coordination with the Project Officer/ technical monitor no later than 90 calendar days after contract award. Also, the successful Offeror, in conjunction with the WTCHP ISSO, is required to update and resubmit its SSP to CDC every three years following the contract award or when a modification has been made to its internal system. In addition to developing and maintaining an SSP, the successful Offeror in conjunction with the WTCHP ISSO shall be responsible for continuously assessing and ensuring information security for the project and for updating the security plan as needed throughout the duration of the agreement.

The SSP is part of the Certification and Accreditation (C&A) process required by the EGovernment Act of 2002 and NIST Special Publication 800-18 and will include selected mandatory controls required by NIST Special Publication 800-53, Volumes I & II. The successful offeror in conjunction with the WTCHP Information System Security Officer (ISSO) will submit C&A documentation to the CDC Chief Information System Officer (CISO). The successful completion of the C&A documents will result in an award of an Authority To Operate. Based on guidance in FIPS 199 and NIST SP 800-60 the system will be assigned an overall security category (SC) of LOW, MODERATE, or HIGH based on (confidentiality, LOW/MODERATE/HIGH), (integrity, LOW/MODERATE/HIGH), and (availability, LOW/MODERATE/HIGH) impact levels. These impact levels will be initially determined by the WTCHP ISSO and confirmed by the CDC OCISO Certifying Authority as part of the Certification and Accreditation process.

The successful Offeror is responsible for providing pertinent security information to the WTCHP ISSO and Security Staff and assisting in completing the below CDC Certification and Accreditation documents. Appropriate security templates will be provided to the successful Offeror by the WTCHP Security Staff. Completed documents will be sent to the CDC Chief Information Security Office (CISO) for review, approval and subsequent issuance of an Authority To Operate (ATO). Examples of the documents that will be compiled for the C&A package are:

- Baseline System Information (BSI)
- Privacy Impact Assessment (PIA)
- Host Characterization Worksheet (HCW)
- System Security Plan (SSP)
- Security Baseline Worksheet (SBW)
- Business Continuity Plan (BCP)
- Risk Assessment Report (RAR)

The Offeror shall respond to the following seven security-associated requirements in their proposal:

**(1) Position Sensitivity Designations**

CDC requires a Public Trust Level 5 for the following:

The following position sensitivity designations and associated clearance and investigation requirements apply under this licensing contract:

Level 5: Public Trust - Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI). Licensor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI). Upon award, the Licensor will be required to submit a roster of all staff (including sub-offeror staff) working under the contract that will have the ability to access sensitive WTCHP information from the system. The roster shall be submitted to the Project Officer/technical monitor, with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. Any revisions to the roster as a result of staffing changes shall be submitted within 15 calendar days of the change. The Contracting Officer shall notify the licensor of the appropriate level of suitability investigations to be performed, but Licensor employees and subcontractors who have met investigative requirements within the last five years may only require an updated or upgraded investigation. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for offeror use at: <http://ais.nci.nih.gov/forms/Suitability-roster.xls>. Upon receipt of the Government's notification of applicable suitability investigations required, the Licensor shall complete and submit the required forms within 30 days of the notification.

**Non-Disclosure Agreements** - The Offeror and any sub-Offerors or employees are forbidden from sharing any technical or logistical information they may gain in conjunction with matters related to this task order that could jeopardize the physical or information security of CDC or its employees, projects, or information systems.

The following conditions apply to Licensor employees and their subcontractors associated with the project:

- 1) Personnel may not begin work under the contract until the contractor has submitted the employee roster and non-disclosure agreements as described above.
- 2) Personnel without necessary background investigations will not have access to sensitive project data.
- 3) Violation of these conditions may lead to termination of the contract.

It is the Offeror's responsibility to ensure that all employees have met CDC and federal requirements, such as, for example, completion of background checks, before gaining or utilizing access to CDC information technology resources.

## **(2) Privacy Compliance**

Licensor in conjunction with CDC Center ISSO and the CDC Chief Privacy Officer shall conduct and maintain an initial Privacy Impact Assessment (PIA) as defined by Section 208 of the E-Government Act of 2002. Periodic reviews shall be conducted by the system owner, with assistance from the CDC Center ISSO, CDC Chief Privacy Officer and offeror, to determine if a major change to the system has occurred, and if a PIA update is needed.

## **(3) Offeror's Official Responsible for Information Security**

The offeror shall include in the "Information Security" part of the Technical Proposal the name and title of its official who will be responsible for all information security requirements should the offeror be selected for a contract award.

## **(4) Rules of Behavior**

The offeror's employees and subcontractors shall comply with the HHS Information Technology General Rules of Behavior.

## **(5) Information Security Training**

HHS policy requires that contractors and subcontractors shall receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements. The successful offeror shall be responsible for ensuring that each employee, including subcontractors, has completed the HHS Computer Security Awareness Training course (or another course designated by CDC) prior to performing any contract work, and thereafter completing the HHS-specified annual refresher course during the period of performance of the contract. This would be provided at the Offeror's expense and would be the Offeror's responsibility to plan and arrange. The successful offeror shall maintain a listing of all individuals who have completed this training and shall submit this listing to the project officer.

**(6) HSPD-12 Compliance**

Federal Information Processing Standard 201 (FIPS-201) (vii) compliant, Homeland Security Presidential Directive 12 (HSPD-12) card readers shall: (a) be included with the purchase of servers, desktops, and laptops; and (b) comply with FAR Subpart 4.13, *Personal Identity Verification*.

**(7) Encryption**

All sensitive CDC-funded data stored on desktop computers used on behalf of HHS shall be secured either through a FIPS 140-2 compliant encryption solution or through adequate physical security and operational controls at the desktop's residing location.

All mobile devices, portable media and transfer data files that contain sensitive CDC program-funded data shall be encrypted using a FIPS 140-2 compliant algorithm.